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The Maryland Pharmacist

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Dean E. Leavitt, Ph.D.
1929–1989

Maryland Pharmacists Association Constitution and Bylaws

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET
BALTIMORE MARYLAND 21201
TELEPHONE 301/727-0746

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Commentary

SeniorReach

Maybe you have experienced it before. You need help but don't know where to find it. You may be a senior citizen or a relative of an older person. You feel frustrated because someone you know needs help, and although you have made several phone calls, you still have not found the help you need. It happens to almost everyone. Older persons may need help with particular problems, such as, health care, housing, transportation, resource management; or they want information to help plan for future years.

Recognizing the need to increase public awareness of services and benefits available to persons 60 and over, the Maryland Office on Aging is initiating a statewide extensive informational campaign known as SeniorReach. Our goal is to reach all segments of the older population and their families with information about services and benefits available to persons age 60 or over.

To accomplish this goal, the Maryland Office on Aging announces its partnership with the Maryland Pharmacists Association. The Maryland Pharmacists Association will provide detailed information in the monthly journal about the programs and benefits available to the elderly throughout the State, and stickers or bookmarks will be used to inform our customers about where to turn for help. Each article will discuss issues of concern to older persons and their families. Some of the subjects to be discussed will include: Employment Opportunities, Good Nutrition for Seniors, How to plan for Long Term Care, Housing Options and Opportunities, Weatherization and information on Taxes. (As these articles are published I hope readers will feel free to send me their comments, questions and recommendations).

And now back to the problem of finding the services you need. Senior Information and Assistance is a statewide program providing 191 ''one-stop'' centers for information about services and benefits for older persons. The goal of Senior Information and Assistance is to match services to the needs of seniors. These offices also assist in determining the need for services and refer you to the agencies that provide such services and benefits. Senior Information and Assistance staff then follow-up to make sure that you receive all the services available. Help is only a phone call away.

Rosalie Silber Abrams

DIRECTOR

MARYLAND OFFICE ON AGING

Editors Note: The 24 main offices for Senior Information and Assistance are listed on page 28 of this issue.

Counseling Consumers on OTC Pregnancy and Ovulation Tests

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio
and
Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to:

1. describe important points about home testing products for pregnancy and ovulation; and
2. explain points of consumer information about these products to assure that test results will be accurate.

Objectives

At the conclusion of this lesson, participants will be able to:

1. select the chemical and physiological basis for which home testing products for pregnancy and ovulation are based;
2. exhibit an understanding of the reasons why false positive and false negative responses occur;
3. choose from a list of products, appropriate ones when given specific criteria;
4. demonstrate knowledge of the theory of using basal temperature measurement to predict the time of ovulation; and
5. choose from a list, points of consumer information required to correctly perform the tests.

Women can choose from a variety of OTC home testing products to determine pregnancy and to assess when ovulation will occur. These home tests are based on sound chemical and physiological principles, are relatively simple to use, and their results are accurate.

Home testing products for pregnancy and ovulation are similar in design and applicability to procedures that physicians and clinical laboratories use. But the directions must be carefully and completely followed to assure accurate test results.

Historical Perspective

Pregnancy. Fourteenth century B.C. Egyptian papri instructed a woman who wanted to confirm her pregnancy to sprinkle urine over barley and wheat seeds. According to legend, if the barley seeds grew, she would deliver a girl. If the wheat seeds grew, she would bring forth a boy. If neither seed germinated, she was not pregnant.

During the golden age of Greek medicine, Hippocrates wrote: ''If a woman has not conceived, and you wish to determine whether conception is possible, wrap her up in a cloak, and burn incense underneath. If the odor passes through the body to the nose and mouth, then she is not sterile.''

A 1776 English publication entitled *Aristotle's Last Legacy* proclaimed: ''Keep the urine of a woman closed in a glass three days, and then strain it through a fine linen cloth. If you find small living creatures in it, she is most assuredly conceived with child; for the urine which is before part of her own substance will be generated as well as its mistress.''

The biological era of urine testing for pregnancy began in 1928. The test procedure utilizd animal tissues to detect the presence of human chorionic gonadotropin (hCG) in the urine. This hormone is produced by the placenta after an ovum (egg) has been fertilized and implanted in the endometrium. Its function is to maintain the corpus luteum and keep progesterone production relatively high to support vascularization of the endometrial wall. It also curtails pituitary production of follicle stimulating hormone (FSH) and luteinizing hormone (LH), therby preventing another ovum from being released and competing with the developing fetus.

The test was performed by injecting the woman's urine into a female rat. The animal was sacrificed after 5 days, and its uterus removed and weighed. A heavy uterus indicated that hCG was present in the urine, and hence, that the woman was pregnant.

Over the years, other animal species were substituted for the rat because they required less time to complete the test. For example, rabbits displayed a similar response in 48 hours. African toads responded within a few hours after injecting urine containing hCG by laying eggs or releasing sperm, depending on their sex.

The disadvantages of biological assays are obvious. Sacrificing animals is expensive, and some believe unnecessarily cruel. African toads are difficult to obtain. And biological assays are plagued with the same broad variability of results associated with other forms of animal experimentation. Animal tests also yield a high false negative response rate.

The modern immunochemical assays for detecting pregnancy replaced the older methods beginning in 1960. They are cheaper, generally require only minutes to a few hours to perform, and are more accurate.

Ovulation. Through the years, women have also attempted to predict their time of ovulation by using a variety of evaluative means. None were reliably accurate. Basal (resting) metabolic temperature measurement has been used as a predictor since the early 1900s. A rise in the basal body temperature occurs approximately one day after the surge of LH from the pituitary.

Recall that LH is the hormone that initiates the mature graffian follicle in the ovary to release an ovum into the fallopian tube to await fertilization. It also supports the corpus luteum which, in turn, secretes high levels of progesterone to make the endometrial lining more receptive to implantation and to maintain growth of the fertilized ovum. Following conception, hCG assumes this role.

The problem is that information obtained by measuring the basal metabolic temperature only suggests that a woman has already ovulated, approximately one day earlier. Although basal metabolic temperature monitoring has been widely used and is simple to perform, the procedure has limited value and results are subject to considerable error.

Basal Temperature Measurement. The basal temperature is the lowest body temperature that occurs while awake. In healthy women, it is recorded upon awakening from a restful sleep, before initiating mental or physical activity.

The basal thermometer measures body temperature between 96° to 100° F. By limiting the range of temperature readings, there is a wide span between each 0.1° mark on the thermometer. This makes it easier and more accurate to measure slight temperature variations.

For the first fourteen or so days of each menstrual cycle, the basal temperature fluctuates only slightly. When ovulation occurs, the temperature first drops 0.4° to 1°, then spikes 0.5° to 1° above the pre-ovulation period. It remains elevated until menses occurs.

To properly use the basal temperature ovulation testing method, the woman should chart her daily body temperature for at least 4 months to get a control level. She should take it immediately on awakening, before arising from bed, drinking, talking or smoking. A chart is supplied with each basal thermometer and should be used as instructed.

The woman should be advised to shake the thermometer down to a reading below 95.5° the night before each reading, since any degree of physical activity can affect the basal temperature. The thermometer can be used orally or rectally, but the former is preferred. It should remain in place for 5 minutes, before removing and the reading recorded.

Numerous other assessments have also been employed by physicians to predict timing of ovulation. These include determining changes in the morphology of the cervix and assessing its quantity and quality; measuring estrogen, progesterone and LH levels; and detecting temperature changes on the breast. All of these methods have some utility and are applicable to specific situations. But assaying for urinary LH has proven to be the most useful of all of the tests, and this serves as the foundation for modern OTC ovulation testing products.

OTC Ovulation Tests

The physiological basis for these self-tests is that ovulation normally occurs as midcycle, fourteen days after onset of the previous menses. It is triggered by a sudden surge in release of LH from the pituitary, which spikes approximately 24 hours prior to ovulation. This increased concentration spills over into the urine where it can be detected.

OTC tests for ovulation (Table 1) enable women to predict when they will ovulate. This information can be used to increase the chance of pregnancy. By knowing when ovulation is most likely to occur, coitus can be planned accordingly.

TABLE 1
OTC ovulation testing products

Product	Manufacturer
First Response Ovulation Predictor Test	Tambrands, Inc.
OvuSTICK Self-Test	Monoclonal Antibodies, Inc.
Ovutime	Ortho Pharmaceutical Corporation
Q Test for Ovulation Prediction	Becton Dickinson

They can also be used to assist in minimizing the chance of pregnancy. Coitus can be avoided, or extra contraceptive measures taken during the fertile period.

The products share an important limitation when used to avoid pregnancy. An unwanted pregnancy can occur, even though the testing product accurately predicted the time of ovulation. Sperm remain viable within the female genital tract for up to 72 hours. If the test predicted on day 13, for example, that ovulation would occur on day 14, sperm that had been deposited as early as day 11 might still fertilize an ovum 3 days later. Also, unprotected coitus should be avoided for 3 days following ovulation to minimize the chance of pregnancy.

OTC Pregnancy Tests

If an ovum is fertilized and becomes implanted in the endometrium, sufficient hCG will be produced so

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that detectable amounts can be found in the woman's urine within about 9 days. By this point, she has not missed a period because menses would not normally occur for another 5 days. Human chorionic gonadotropin production doubles every 2 weeks to peak at the 8th to 10th week of pregnancy. The level then decreases afterward. The hormone is a specific marker for pregnancy, because in healthy women, it is only synthesized in significant amounts by the placenta.

Hormone levels are highest in the morning between 9:00 a.m. and noon because renal activity is greatest during this time. Manufacturers of home testing products recommend that an early morning urine sample be used to assure the most accurate results.

Urinary hCG can increase even in the absence of pregnancy, when chorionic tumors such as hydatid disease or choreocarcinoma are present. OTC testing products will detect such tumors in females, and in males who have choreocarcinoma of the testes. The hormone is not normally present in significant amounts in males after birth. Therefore, its quantification provides a useful measure of tumor progression or regression in men.

It should be noted that an accurate test for early detection of pregnancy must be sensitive, but at the same time provide minimal false negative and false positive responses. To be competitive among other products, the test must be easy to perform in a short period of time, be readily available, be easily reproducible and relatively inexpensive.

Early pregnancy detection can help a woman avoid drugs and chemicals, and exposure to x-rays or elective surgery that are potentially harmful to the fetus. Cellular differentiation and development of embryonic organ systems occur during the first trimester of pregnancy, and the fetus is most susceptible then to toxicity. The first 8 weeks are the most critical, and neither the woman nor her physician may be aware of her pregnancy status that early.

The earliest home pregnancy testing products contained **polyclonal** antibodies that recognized several binding sites on hCG. They were also reported to react with other substances such as LH and FSH, to give false positive results.

Newer pregnancy testing products (Table 2) employ state of the art **monoclonal** antibody technology. Monoclonal antibodies are sensitive to a single binding site on the hCG molecule. They do not react with other substances and they are more accurate.

TABLE 2
Selected newer home testing products for pregnancy

Product	Manufacturer
Advance	Ortho Pharmaceutical Corporation
Answer Plus	Carter Products
Clearblue	VLI
e.p.t. Plus	Warner-Lambert Company
First Response Pregnancy Test	Tambrands, Inc.
Q Test for Pregnancy	Becton Dickinson

OTC pregnancy tests can be grouped as first or second generation products. **First generation tests** work on the principle of hemagglutination inhibition. To use them, the woman incubates a urine sample with the test product reagent that includes sheep RBC's coated with hCG and rabbit anti-hCG serum. If hCG is present in sufficient concentration to neutralize the antiserum, the RBCs will not agglutinate. Instead, they will settle to the bottom of the test tube in a doughnut-shaped pattern indicating a positive test. If the antibody is not neutralized (negative test), agglutination results in a diffuse mat of cells at the bottom of the tube. The most sensitive of the first generation home testing products detects hCG as early as the third day of a missed menstrual period.

The **second generation OTC pregnancy testing products,** which are even more sensitive, utilize monoclonal antibodies and detect hCG as early as the first day of a missed menstrual period. Whereas the first generation tests require up to 60 minutes to perform, one of the newer tests requires only 10 minutes to obtain a response. Second generation testing products are also generally easier to use.

TABLE 3
Factors that interfere with home pregnancy test products

False Negative Responses
- Test conducted too early or too late during gestation
- For first generation tests: test tube and reagents jarred during the incubation period

False Positive Responses
- Soap or detergent residues in the urine collection container
- Blood or protein in urine*
- Test conducted in missed or incomplete abortion
- Ectopic production of hCG by non-trophoblastic tumors (e.g., carcinoma of lung)
- Test conducted in postmenopausal women
- For first generation tests: drugs such as phenothiazines and oral contraceptives (see text)

* Not significant for second generation test products

How Accurate are the OTC Pregnancy Tests?

Some manufacturers' package inserts claim their products possess an accuracy of approximately 98 percent, even when the tests are performed by women who are untrained in diagnostic procedures. There are numerous factors which may lead to underlying false negative or false positive results. Table 3 summarizes important points. The most common cause of a false negative response is performing the test too early or too late in gestation when hCG levels may be insufficient to detect. Manufacturers advise users who obtain a negative test to confirm the result by repeating the test one week later.

False positive test results can be caused by contamination of the reagents or urine collection containers. In the case of a missed or incomplete abortion, a significantly elevated hCG level may remain in the urine for 1 to 2 weeks afterward. A test performed at this time will yield a false positive result.

The first generation tests do not distinguish between gonadotropins from pituitary or chorionic origin. Postmenopausal women and others who take drugs which stimulate hCG production may get a false positive response. False positive responses are rare with the second generation testing products. Some phenothiazine derivatives (e.g., Thorazine, Stelazine, Trilafon, Vesprin, and Mellaril) are documented causes of false positive results with the hemagglutination inhibition tests. Phenergan has been reported to cause a false negative result with these tests.

A major deficiency of the home pregnancy and ovulation testing product is a lack of quality control in the reagents used. Test kits should ideally contain one control reagent which would provide a positive test, and another which would give a negative result. These controls would allow the user to check the test product's reagents for stability and sensitivity.

An interesting question regards whether a woman can accurately assess if she is pregnant, without using a diagnostic test. In other words, are the tests more accurate than female intuition?

To answer, 283 women who requested a pregnancy test from a physician because of late menses were questioned as to their feelings about the possibility of pregnancy. Two hundred four (72 percent) of the women believed they were pregnant, but only 109 (53 percent) tested positive. Of the women who believed they were not pregnant, 90 percent were accurate.

Counseling Consumers

OTC testing products for pregnancy are not intended to replace a physician's diagnosis. Manufacturers' instructions strongly stress that users contact a physician immediately if they get a positive test result. This should be reinforced to all OTC pregnancy testing product purchasers. Users should also be told to consult a physician even though they obtain one or more negative test results, if they still think they are pregnant, and their menstrual period is more than 7 days overdue. A negative urine test result merely implies that hCG is not present in detectable quantity. It does not mean that the woman is not pregnant. A positive response indicates a probably, but not absolute, sign of pregnancy.

Pharmacists can provide a professional service by explaining to consumers how the testing products work, and make sure that they understand the variables which may lead to erroneous results. It is unfortunate that not all of the products list these factors in their directions.

Women should be instructed to read and follow directions carefully, and to ask a pharmacist or physician for assistance if some steps are not clear. Instructions for using the home testing products are not interchangeable among different products. Some pregnancy testing products instruct the user to gently shake the reagents, for example, while others state that the user should shake the reagents vigorously. Still others state that they should not be shaken at all.

It is best to use early morning urine samples. These contain the highest concentration of hCG and LH, assuming the bladder has not been emptied for the past 6 to 8 hours. Urine should be collected in a clean, dry, detergent-free container, preferably the one supplied with the product. It should be tested immediately after collection. If this is not possible, urine may be refrigerated for up to 12 hours before testing.

If refrigerated, urine should not be frozen, as hCG and LH can be denatured upon thawing. It should not be shaken if a sediment occurs. Instead, the clear upper (supernatant) portion should be removed for testing. Urine that is colored pink or red, appears cloudy, or has a strong odor should not be used.

Vibrating the tube or exposing it to direct sunlight during the waiting period may affect formation of the ring for the first generation tests. The tube should, therefore, not be left on or near a vibrating appliance such as a refrigerator, dishwasher or food processor.

1989 USP CATALOG AVAILABLE

The United States Pharmacopeial Convention, Inc. (USP) announces the release of the *1989 Catalog of Publications and Services* containing complete descriptions and ordering information for all publications, computer applications, and services available from the USP.

The 32-page *USP Catalog* is divided into sections titled Drug Information, Patient Education, Computer Applications, Drug Standards, and Other Services. It provides in-depth information on the USP DI System, including the new *USP DI* Volume III, *Approved Drug Products and Legal Requirements*, and the vastly expanded USP Leaflet Diskette. It also announces the upcoming publication of the new edition of *USP XXII—NF XVII*, due July 1, 1989.

As a comprehensive reference to the various operations within USP, the 1989 USP Catalog also provides information on services such as USP Reference Standards, student programs, and the USP Drug Product Problem Reporting Program (including actual forms for reporting). The 1989 USP Catalog is a valuable resource for those involved in the purchase and/or recommendation of drug information publications and patient education materials.

The *1989 Catalog of Publications and Services* is available free of charge by writing to USP Catalog, 12601 Twinbrook Parkway, Rockville, MD 20852, or by calling toll-free at 1-800-227-8772. Requests for the catalog may also be sent by FAX to 1-301-881-5021.

THE UNIVERSITY OF MARYLAND

SCHOOL OF PHARMACY

Phonathon sets record

November's five-day phonathon for the 1988–89 School of Pharmacy's Annual Fund raised $30,088 in pledges. This represents a 56 per cent increase over last year's phonathon and puts the school well on its way to raising its goal of $100,000 to support unfunded programs and activities.

According to Jacquie Lucy, director of Alumni/Public Affairs, "This year, we tried several new strategies to reach more alumni donors: moving to a fall phonathon; extending the calling hours until 10 p.m.; adding a Sunday call day; and increasing the number of student callers." One major secret of the phonathon's success was that Maryland's Phi Delta Chi chapter adopted the phonathon as a project, and its members provided a new and competitive source of callers.

As of December 10th, 224 (36 per cent) of the pledges to the phonathon had been paid in full.

SCODAE goes national with major grant

SCODAE (the Student Committee on Drug Abuse Education) has received a two-year grant of $220,000 from the U.S. Department of Education's Fund for the Improvement of Post-Secondary Education to take its innovative approach to drug education to pharmacy schools across the nation. SCODAE trains pharmacy students to lecture on drug abuse topics to elementary and secondary schools students as well as to health and education professionals. SCODAE also produces **PharmAlert**, a quarterly newsletter on drug abuse topics.

This grant will support the production and distribution of SCODAE teaching materials and will allow SCODAE members to participate in several national meetings to market the program to pharmacy students and faculty of other schools and set up regional training session next summer.

In conjunction with this national focus, Tony Tommasello, the director of SCODAE, and SCODAE chairman and senior pharmacy student Noel Wilkin developed the new red, white and blue logo for SCODAE.

Margaret Beatty retires . . . sort of

Margaret Beatty, executive administrative aide to the Dean, has begun partial retirement after 40 years of service as the secretary in the Dean's Office. Over the years, Ms. Beatty has worked for acting dean B. Olive

Continued on page 24.

Pneumonia: An Old, Still Deadly Nemesis

Pneumonia—the sixth leading cause of death in the United States—kills more people than any other infectious disease including AIDs, according to the National Foundation for Infectious Disease.

Pneumonia's high economic cost is equally startling. The National Heart, Lung and Blood Institute estimates direct and indirect costs of pneumonia at $4.8 billion a year. In 1985, among adults 18 years of age and older, pneumonia accounted for more than 5.3 million work days lost.

What Is Pneumonia?

Pneumonia is a serious lung infection that interferes with the body's ability to take oxygen from air and send it into the blood stream. The disease dates to at least the second century A.D., and derives its name from the Greek verb pneo, meaning to breathe or draw breath.

Half of all pneumonias are caused by viruses (viral pneumonia), the other half by bacteria (bacterial penumonias). These microbes enter and multiply in the lungs, causing air sacs (alveoli) to collapse and release fluid. This fluid serves as food to invading germs, allowing them to spread to other lung sections. If left untreated, permanent lung damange can result.

Who Is At Risk?

Pneumonia can afflict anyone, but it is particularly dangerous for the very young, the chronically ill and the elderly; it is the fourth leading cause of death for those 65 and older.

Pneumonia most frequently occurs when the body's defenses are weakened by illness, impaired immunity or malnutrition. These factors allow the bacteria and viruses, which the body's natural defense mechanisms normally ward off, to invade the lungs.

Patients hospitalized for other illnesses are also susceptible to nosocomial, or hospital-acquired, pneumonia. Nosocomial pneumonia accounts for 10 percent of the two million yearly reported cases of hospital-acquired infections. These pneumonia cases can extend a patient's hospital stay by an average of four days, resulting in approximately $1,700 in excess costs.

Pneumonia can be especially life-threatening for heavy smokers, cancer patients, alcoholics, drug addicts and cystic fibrosis and asthma patients, as well as those with chronic heart and lung disease, diabetes, kidney failure, impaired spleen or liver function and sickle cell disease.

Symptoms

Symptoms of pneumonia can develop gradually or appear quite suddenly. For bacterial pneumonia, symptoms usually include high fever, sweating, chills, severe chest pain, cough with sputum (sometimes blood-tinged or greenish) and rapid breathing and pulse rate.

The common symptoms of viral pneumonia often imitate those of influenza, including fever, dry cough (sometimes with a small amount of bloody sputum), headache, muscle pain and prostration. There may also be nausea and vomiting.

Diagnosis and Treatment

Physicians use chest x-rays and analysis of blood and sputum to confirm a diagnosis of pneumonia. For most patients, an early diagnosis can greatly increase the likelihood of recovery. Death due to pneumonia can clearly be related to delay in seeking medical care.

A thorough medical history and careful interpretation of test results is needed to identify the cause. This information is critical as various bacteria and viruses respond differently to different treatments.

Mild forms of pneumonia are usually treated with oral antibiotics, such as penicillins and erythromycins. More serious cases may require hospitalization for intravenous (IV) antibiotics, such as cephalosporins and aminoglycosides. The new oral quinolone antimicrobial, CIPRO (ciprofloxacin/HCl Miles), is also indicated for treatment of lower respiratory tract infections, including pneumonia.

CIPRO is most useful in those cases where the efficacy of traditional therapies, such as cephalosporins or erythromycins, may be in doubt. Because it is as effective as IV therapy, CIPRO can often replace this type of expensive therapy. With oral CIPRO, many patients can avoid the inconvenience and problems often associated with IVs.

Antibiotics should only be taken under the direction of a physician. Even if the patient feels better, he should complete the full course of therapy as prescribed by the physician to ensure that the infection is entirely cured and does not recur.

Plent of rest and a good diet for the patient also aid recovery.

Prevention

Most normal, healthy adults have a low risk of contracting pneumonia. Reduction in smoking is a major factor in improving lung function and in minimizing the risk of pneumonia. A well-balanced diet with plenty of fluids can also help guard against infection.

A number of highly effective vaccines against pneu-

Pneumonia Mortality

All Races, Male	32,422
All Races, Female	33,139
White Male	28,347
White Female	30,214
Black Male	3,616
Black Female	2,631

Race/Sex	Age			
	Under 19	20-39	40-64	65 +
White Male	410	512	2,799	24,431
White Female	324	287	1,683	27,898
Black Male	199	283	969	2,157
Black Female	152	160	453	2,464

	Under 19	20-39	40-64	65 +
All Races, Male	609	795	3,768	26,588
All Races, Female	476	447	2,136	30,362
All White	734	799	4,482	52,329
All Black	351	443	1,422	4,621

***SOURCE:** National Center for Health Statistics, **Vital Statistics of the US,** 1985, Volume II-Mortality. Published by the U.S. Dept. of Health and Human Services. Supplied by Miles Inc. Pharmaceutical Division.

mococcus pneumonia are available; there is also a vaccine for influenza which must be obtained every year.

The influenza vaccine is usually recommended for persons who are at increased risk including: those age 65 or older; persons with chronic illnesses, such as lung, heart and kidney disease; patients recovering from a severe illness; and those living in a nursing home or other chronic-care facility.

The vaccine is usually given in October or November—the start of pneumonia/influenza season. Immunization will usually develop two or three weeks after vaccination.

Use the column below on Consumer Tips as an informational leaflet for your patients, especially for the elderly and infirm.

CONSUMER TIPS ABOUT PNEUMONIA

1. KNOW THE SYMPTOMS OF PNEUMONIA:

- high fever plus severe cough
- pink or bloody sputum
- chest pain
- shortness of breath
- rapid breathing and pulse rate

The earlier you detect the signs, the more easily pneumonia can be cured.

2. CONSULT YOUR DOCTOR ABOUT FLU AND PNEUMONIA VACCINES IF YOU:

- are over age 60
- suffer from chronic heart condition
- have respiratory problems
- have kidney disease or diabetes

3. TELL YOUR DOCTOR ABOUT ALL THE MEDICAL CONDITIONS YOU HAVE, SUCH AS: DIABETES AND OTHER RESPIRATORY DISEASES (ASTHMA, BRONCHITIS)

4. BE AWARE THAT OLDER PEOPLE (over age 60) ARE MORE SUSCEPTIBLE TO PNEUMONIA BECAUSE:

- their immune systems are often less able to fight off infections
- their pre-existing chronic conditions such as heart disease and diabetes often worsen infection
- common symptoms of pneumonia are often vague or absent in the elderly

5. MAINTAIN YOUR HEALTH:

- eat a well balanced diet
- get plenty of rest
- don't smoke

IF YOU EXPERIENCE ANY SIGNS OF PNEUMONIA, SEE YOUR DOCTOR IMMEDIATELY

Three Million Catch Pneumonia Annually:

Nearly three million Americans will get pneumonia this fall and winter; one million will be hospitalized for it. Each year, the number of deaths caused by pneumonia rises.

"Pneumonia is a serious problem, particularly for the chronically ill and elderly," says Harold C. Neu, M.D., chief of infectious diseases, Columbia University, New York. "Vaccines against influenza and pneumococcal pneumonia can prevent certain types, but once you've contracted pneumonia, antibiotics are the major treatment."

"The chance of acquiring pneumonia and dying from it increases dramatically with age," Dr. Neu adds. "People over age 60 are twice as likely to catch pneumonia as younger adults and twice as likely to die from it." For the elderly, penumonia mortality rates are close to 30 percent compared to a 10 to 15 percent average for the entire population.

Pneumonia is the sixth leading cause of death, killing nearly 65,000 Americans annually, according to the National Center for Health Statistics (NCHS). More than 75 percent—about 51,000—are men and women over the age of 65.

Between 1982 and 1986, death from pneumonia and influenza rose 40 percent in the U.S., primarily due to several influenza outbreaks, according to statisticians at Metropolitan Life Insurance Company. Pneumonia–one of the main complications associated with influenza—accounted for almost all the deaths.

Prevention

Pneumonia is caused by bacteria or viruses. It often strikes when a person's defense system breaks down, after a bout with the common cold or flu, for example, or when a person is not eating properly. While prevention is difficult, following these guidelines can help:

- Eat a well-balanced diet;
- Drink plenty of fluids;
- Don't smoke;
- Get plenty of rest;
- Avoid close hand contact with people who have the flu;
- Avoid excess alcoholic beverages if you have a viral illness.

People over 60 should consult their doctor about getting a vaccine against bacterial pneumonia; above all, older persons should get the influenza vaccine because if they contract influenza they will be predisposed to bacterial pneumonia.

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an ALCO HEALTH SERVICES company

ATTENTION
MR. INDEPENDENT RETAILER

BELOW ARE 7 IMPORTANT QUESTIONS THAT COULD EFFECT THE FUTURE OF YOUR PHARMACY.

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2. ARE YOUR PRESCRIPTION CUSTOMERS BUYING THEIR HBA'S FROM YOUR COMPETITION? (CHAINS, MASS MERCHANDISERS, GROCERY STORES)
3. ARE YOUR HEALTH AND BEAUTY AIDS PRICES COMPETITIVE?
4. IF SO, ARE YOU TELLING YOUR CUSTOMERS?
5. HAS INCREASED THIRD PARTY PRESCRIPTIONS AND COMPETITION AFFECTED YOUR PRESCRIPTION DEPARTMENT PROFIT?
6. ARE YOU TIRED AND CONFUSED FROM SEARCHING FOR THE BEST SOURCE OF SUPPLY, AT THE BEST PRICE, TO FILL YOUR O.T.C. AND PHARMACEUTICAL NEEDS?
7. ARE YOU INTERESTED IN A TOTAL PROGRAM THAT WILL SOLVE ANY OR ALL OF THE ABOVE?

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PATRICK L. HRUZ
SALES MANAGER

Symptoms

Depending on what organism is causing the pneumonia, symptoms can appear gradually or quite suddenly. The most common signs of pneumonia are:

- high fever;
- severe cough with sputum;
- sharp chest pain;
- shortness of breath;
- rapid breathing and pulse rate.

If any or all of these symptoms appear, especially after a mild cold or flu, a person should see a doctor immediately. A relapse after a bad cold or flu is particularly significant. Its appearance, when one should be getting better, is very suggestive of pneumonia.

Treatment

Oral antibiotics, such as penicillins and erythromycin, are the traditional treatments for mild pneumonia. More serious cases may require hospitalization for other antibiotics that are given by vein (IV).

According to Dr. Neu, these traditional IV antibiotics remain effective for pneumonia-causing bacteria, such as *pneumococci* and *staphylococci,* but the extensive, although appropriate use of older oral antibiotics has caused more resistant bacteria to become a problem in the hospital. It has been determined that bacteria such as *Haemophilus influenzae* and *Branhamella catarrhalis,* which are major causes of bacterial bronchitis during the winter, make enzymes that destroy older antibiotics. Bronchitis can progress to pneumonia if not properly treated.

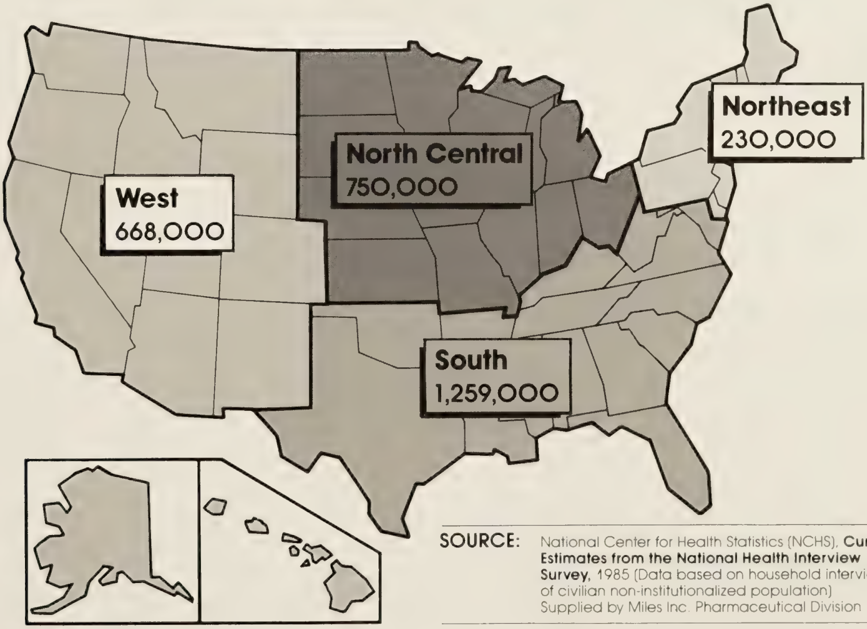
"Oral quinolones such as CIPRO are the newest, exciting group of antimicrobials," Dr. Neu noted. "They have a broad-spectrum of activity that include the majority of bacteria-causing pneumonia and have a potency similar to the best of the IV antibiotics." "Patients who will benefit most include those with infections where the suspected pathogens are likely to be multiple-drug resistant and/or beyond the scope of traditional therapy, and those patients with bronchitis who have responded poorly to other therapies," Dr. Neu continued.

CIPRO is the only oral quinolone currently available for treatment of lower respiratory tract infections. According to Dr. Neu, CIPRO will be helpful not only in patients who have failed traditional-first line therapy, but in those suffering from more difficult infections, such as *Klebsiella, Serratia* and *Pseudomonas,* common, deadly bacteria often seen among the elderly in nursing homes or in the hospital.

Doctor's Orders

Patients suffering from bronchitis or pneumonia should take antibiotics according to the doctor's instructions. Most important, even if the patient begins to feel better, all the pills in the prescription should be taken to prevent pneumonia from recurring.

Number of Pneumonia Cases Nationwide



SOURCE: National Center for Health Statistics (NCHS), **Current Estimates from the National Health Interview Survey,** 1985 (Data based on household interviews of civilian non-institutionalized population)
Supplied by Miles Inc. Pharmaceutical Division

THE LOWER RESPIRATORY TRACT–

More vulnerable to infection in smokers and older adults

Experience counts

Ceclor® Pulvules® 250 mg
cefaclor
think of it first

For respiratory tract infections due to susceptible strains of indicated organisms.

Summary.
Consult the package literature for prescribing information.

Indication: Lower respiratory infections, including pneumonia, caused by *Streptococcus pneumoniae, Haemophilus influenzae,* and *Streptococcus pyogenes* (group A β-hemolytic streptococci)
Contraindication: Known allergy to cephalosporins
Warnings: CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS ALLERGENICITY POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS

Administer cautiously to allergic patients

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis

Precautions:
- Discontinue Ceclor in the event of allergic reactions to it
- Prolonged use may result in overgrowth of nonsusceptible organisms
- Positive direct Coombs' tests have been reported during treatment with cephalosporins
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include
- Gastrointestinal (mostly diarrhea). 2.5%
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] and toxic epidermal necrolysis or the above skin manifestations accompanied by arthritis/arthralgia, and frequently, fever). 1.5%, usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely
- Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertonia, dizziness, and somnolence have been reported
- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1%, and, rarely, thrombocytopenia

Abnormalities in laboratory results of uncertain etiology
- Slight elevations in hepatic enzymes.
- Transient fluctuations in leukocyte count (especially in infants and children)
- Abnormal urinalysis; elevations in BUN or serum creatinine
- Positive direct Coombs' test
- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinitest® tablets but not with Tes-Tape® (glucose enzymatic test strip, Lilly). [061088L]

Additional information available from
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National Forum

Drug Testing in the Pharmacy Workplace

James R. Talley, M.S.
School of Pharmacy
Northeast Louisiana University
Monroe, Louisiana

Numerous studies have confirmed what we as pharmacists already knew, that employees who abuse drugs can be damaging to our pharmacy operations. Employees who are drug users are less productive, prone to absenteeism, job injuries, and thievery in the workplace. Whereas drug abuse is prevalent in all strata of employment, it is of special concern in the pharmacy workplace. A number of employers utilize drug testing and it is estimated that over 50% of the largest U.S. companies now test for drugs. It should be noted that drug testing in the workplace can result in a multitude of legal problems.

As a generalized overview, there are four categories of drug tests:

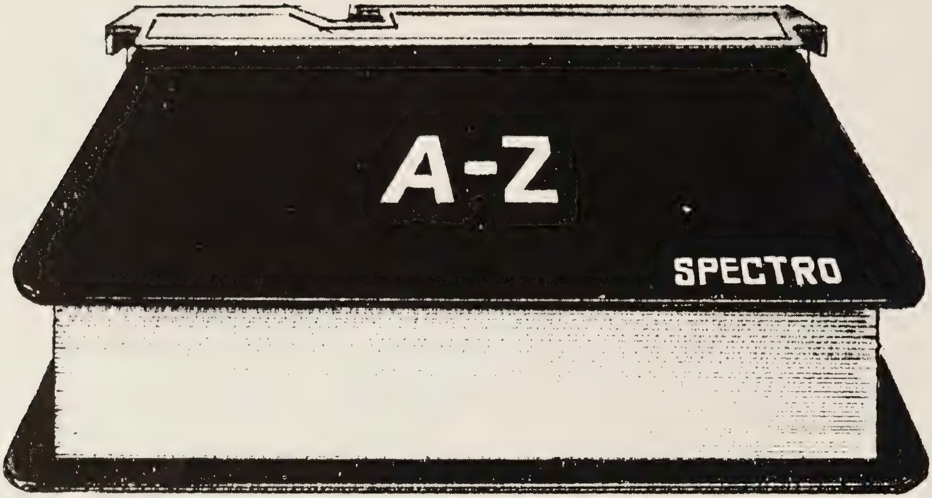
1. **Urine sample analysis:** Unfortunately this testing mechanism can result in false-positive results from a variety of factors. For example, from hangovers; melanin; marijuana smoke-filled air; and poppy seeds.
2. **Blood tests:** These tests are more reliable than urine samples. They can detect and determine minute amounts of drugs in the blood as well as indicate recent usage.
3. **Hair analysis testing:** This mechanism may be useful to determine quantity and history of drug usage.
4. **Brain wave testing:** These tests measure pattern and intensity of electrical conduction between the eyes and the brain. Although this testing mechanism could be useful to detect impairment from drugs, it is not yet technically feasible.

A major issue in regard to drug testing in the workplace is the question of invasion of the right to privacy. Thus, can an employer require an employee to provide body fluids or hair. A second issue concerns false-positive results from tests. A third issue concerns claims of defamation by the employee if the employer improperly disseminates the results of the tests. A fourth issue is whether mandatory testing forces an individual to divulge confidential personal information. A fifth issue concerns employees who do not voluntary consent to testing and whether any action taken against these employees could represent damage claims for invasion of privacy. In a number of states, drug abuse is considered to represent a handicap and is therefore protected by handicap laws.

Notwithstanding all these issues, employers still are adopting policies for drug testing. The following checklist is provided to assist you in regard to developing a drug testing program for your pharmacy:

1. Develop written policies and procedures for drug testing;
2. These written policies should specify legitimate business concerns:
3. These policies should be designed to minimize intrusion on employee privacy and dignity;
4. Obtain employee written consent before testing;
5. Develop written policies for the consequences if an employee refuses written consent;
6. Only test applicants with written consent;
7. Only test employees if there is reasonable suspicion and only after written consent;
8. Train all employees in regard to warning signs of drug abuse;
9. Train all employees in regard to what constitutes reasonable suspicion;
10. Where applicable, obtain written admissions from employees that drug usage is infrequent and not an addiction;
11. Develop evidence of employee performance;
12. Develop evidence of employee safety problems;
13. Use a reliable and well-established laboratory for testing;
14. Use a confirmatory second test for all positive tests;
15. Keep test results confidential;
16. Only disclose test results after the employee has submitted a written request to disclose the test results;
17. Consider employee rehabilitation before initiating discipline or termination;
18. Consistently enforce all drug abuse policies for all employees.

22,000 Items.
Now that's healthy!



You'll find in this book the most comprehensive listing of items available to your pharmacy. You'll also find we can deliver everything we list and do it within 24 hours.

This book is only Volume One in our library. Sales ideas, pricing, services, and time saving procedures, are all contained in the table of contents. Please call us.

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THE HEALTH CARE COMPANY

SPECTRO INDUSTRIES

1989 TAX CALENDAR

The following are due dates for federal and state taxes that will most likely affect you or your organization. Taxes that are due four or more times during the year are identified by abbreviations explained below the chart.

Prepared as a courtesy to Maryland Pharmacists Association Members, by C. W. Amos & Company, Certified Public Accountants with offices in Annapolis (266-9396), Baltimore (727-5341), Bethesda (654-3044), Cambridge (228-7400), Centreville (758-0772), Easton (820-6861), and Salisbury (742-1328).

	January 1989
Thursday, January 5	FD(a)
Friday, January 13	FD(b), FI/SI
Friday, January 20	ST
Tuesday, January 31	FQ, FU, FD(c), SQ, SU Employees' statements W-2 for amounts withheld in 1988 to be furnished by employer. Employer file federal unemployment tax Form 940 for 1988.

	February 1989
Friday, February 3	FD(a)
Wednesday, February 15	FD(b)
Tuesday, February 21	ST
Tuesday, February 28	Forms W-2 "A" copies with transmittal form W-3 filed with Social Security Administration.

	March 1989
Friday, March 3	FD(a)
Wednesday, March 15	FD(b) Federal and state corporate income tax return due or you must pay estimated amount due and file for automatic 6 month extension. Interest will be paid on amount paid after March 16.
Tuesday, March 21	ST

	April 1989
Wednesday, April 5	FD(a)
Friday, April 14	FD(b), FC, FI/SI, SC
Monday, April 17	Federal and State Individual Income Tax due or you must pay estimated amount due and file for an automatic four month extension. Interest will be paid on amount paid after April 17. State personal property tax due.
Friday, April 21	ST
Friday, April 28	FQ, FU, FD(c), SQ, SU

	May 1989
Wednesday, May 3	FD(a)
Monday, May 15	FD(b)
Friday, May 19	ST

	June 1989
Monday, June 5	FD(a)
Thursday, June 15	FD(b), FC, SC, FI/SI
Wednesday, June 21	ST

	July 1989
Thursday, July 6	FD(a)
Friday, July 14	FD(b)
Friday, July 21	ST
Monday, July 31	FQ, FU, FD(c), SQ, SU

	August 1989
Thursday, August 3	FD(a)
Tuesday, August 15	FD(b) Last day for filing tax return or obtaining additional 2 month extension by individuals who obtained an automatic 4 month extension
Monday, August 21	ST

	September 1989
Tuesday, September 5	FD(a)
Friday, September 15	FD(b), FC, FI/SI, SC Last day for filing tax return by corporations that obtained an automatic 6 month extension
Thursday, September 21	ST

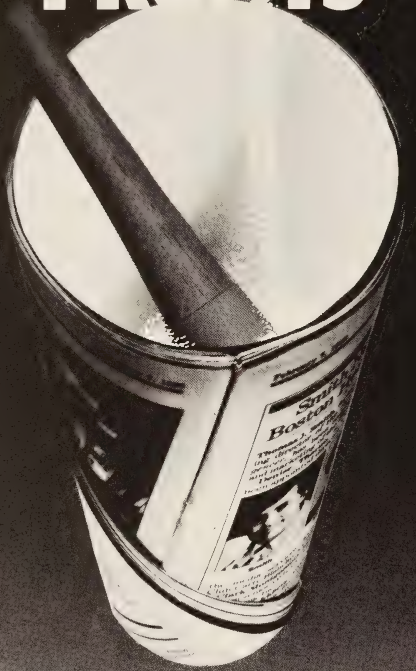
	October 1989
Wednesday, October 4	FD(a)
Friday, October 13	FD(b)
Monday, October 16	Last day for filing tax return by individuals who obtained additional 2 month extension in August.
Friday, October 20	ST
Tuesday, October 31	FQ, FU, FD(c), SQ, SU

	November 1989
Friday, November 3	FD(a)
Wednesday, November 15	FD(b)
Tuesday, November 21	ST

	December 1989
Tuesday, December 5	FD(a)
Friday, December 15	FD(b), FC, SC
Thursday, December 21	ST

FD(a)	Last payment due on federal income and social security taxes withheld during the previous month if over $3,000 was withheld. You are required to deposit the amount withheld within 3 banking days after you reach $3,000 at the end of any eighth-monthly period (these periods end on the 3rd, 7th, 11th, 15th, 19th, 22nd, 25th, and last day of the month).
FD(b)	Federal income and social security taxes withheld must be deposited by this date if between $500 and $3,000 was withheld during the previous month. Earlier deposit is required when $3,000 is reached prior to this date.
FQ	Federal quarterly income and social security taxes withheld must be paid.
FU	Federal unemployment tax must be paid.
FC	Federal estimated corporation taxes must be paid if on calendar basis (note—fiscal year corporations pay this tax on 15th day of 4th, 6th, 9th, and 12th month of their year).
FI/SI	Federal and state estimated individual tax for previous quarter due.
FD(c)	Federal social security and withholding tax due on domestic workers.
ST	Maryland state sales tax due.
SQ	Maryland state income tax withheld due for previous quarter.
SU	Maryland state unemployment taxes due.
SC	Maryland state estimate of corporation tax due.

PERIODICALS COMPOUND YOUR PROFITS



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Maryland Pharmacists Association Constitution and By-Laws

PREAMBLE

I. NAME

This Association shall be known as the Maryland Pharmacists Association and shall be abbreviated "MPhA".

II. OBJECT

The object of this Association is to bring together the pharmacists, pharmacy students and other individuals associated with the practice of pharmacy in the State of Maryland; to advance the interests of pharmacy; to enhance the professional education of all pharmacists; to provide a forum for safeguarding the public health; to promote research in the allied sciences; to seek the enactment of just laws and regulations to guide the practice of pharmacy in the State of Maryland; and to assure that all members maintain their ethics and professional obligations to the public.

III. PURPOSE

To promote the common interest of those engaged in or associated with the practice of Pharmacy in the State of Maryland.

To promote and safeguard the public health and welfare of the people of the State of Maryland.

To foster cooperation in advancing all lawful means of common purposes of its members.

To promote activities designed to improve the professionalism of its members.

To cooperate with other healthcare professionals and organizations.

To promote progress and elevate the standard of professional thought.

To afford due consideration to and expression of opinion upon questions affecting the profession and financial, economic and professional interest of its members.

To promote the proper use of drugs, medicines and healthcare devices.

IV. MEMBERSHIP

Section 1. Active Membership

Any individual in good professional standing who has a valid license to practice pharmacy in any state is eligible to become an active member.

Section 2. Other Categories of Membership

The Board of Trustees shall establish other categories of membership as it deems appropriate.

V. Dues

Section 1. Dues Amount

The annual dues for each category of membership of the association shall be determined by the Board of Trustees.

Section 2. Delinquent Payments

Members who fail to pay their dues within a period specified for each category of membership by the Board of Trustees shall be notified by the Executive Director, and if payment is not made within a grace period, without further notice and without hearing, be dropped from the rolls and thereupon forfeit all rights and privileges of membership. The Board of Trustees may by rule prescribe procedures for extending the time for payment of dues and continuation of membership privileges upon request of a member showing good cause.

Article VI Meetings

General Membership

The Association shall meet at least two times during the year at times set by the Board of Trustees. One meeting shall be known as the Annual Meeting and one shall be known as the Mid Year Meeting.

VII. BOARD OF TRUSTEES

Section 1. Duties and Responsibilities

The Board of Trustees shall provide supervision, control, and direction of the affairs of the Association, shall implement policies established by the House of Delegates, making changes therein if necessary within the limits of the bylaws, shall actively pursue the purposes of the Association and shall have the final discretion in the disbursement of its funds. It may adopt such rules and regulations for the conduct of its business as shall be deemed advisable, and may, in the execution of the powers granted appoint such agents as it may consider necessary.

Section 2. Composition

The Board of Trustees shall be composed of fourteen (14) members which shall include the following officers; Immediate Past President, who shall serve as Chairman; President; Vice President; President-Elect; Speaker and Vice-Speaker of the House of Delegates; Treasurer, six (6) elected Trustees, one trustees who is a member of the Academy of Student Pharmacists of the University of Maryland School of Pharmacy; and the Executive Director (Ex-officio without vote).

Section 3. Terms of Office

Elected Trustees will serve for staggered three (3) year terms, two elected each year. Any Trustee shall be eligible for re-election. Election of Trustees shall be by mail ballot sixty (60) days after nominations have been certified by the House of Delegates. The results shall be reported to the Board of Trustees by a Board of Canvassers appointed by the President. Newly elected Trustees, upon installation, immediately enter upon the performance of their duties and shall continue in office until their successors shall be elected and installed, or unless they resign, are removed, or are otherwise unable to fulfill an unexpired term.

Section 4. Meeting of the Board of Trustees

The Board of Trustees shall have a regular meeting throughout the year, including a meeting at the time and place of the Annual Meeting. The Board shall meet upon call of the Chairman of the Board, or President at such times and places that may be designated, and shall be called to meet upon demand of a majority of the Board. Notice of all meeting of the Board of Trustees shall be sent by mail or other modes of transmittal to the recorded address of the Board members at least ten (10) days in advance of such meetings. With the exception of executive sessions, where confidential issues are discussed, all regular meetings of the Board of Trustees are open to the general membership.

Section 5. Quorum

A majority of the whole Board (eight members) shall constitute a quorum at any meeting of the Board.

Section 6. Absences

If a trustee is absent from three (3) consecutive meetings for reasons which the Board has failed to declare to be sufficient, resignation shall be deemed to have been tendered and accepted.

Section 7. Compensation

Trustees as such shall not receive any compensation for their services as Trustees, but the Board may, by resolution, authorize reimbursement of expenses incurred in the performance of their duties. Nothing herein shall preclude a Trustee from serving the Association in any other capacity and receiving compensation for such services.

Section 8. Resignation or Removal

Any Trustee may resign at any time by giving written notice to the President, the Executive Director or to the Board of Trustees. Such resignation shall take effect at the time specified therein, or, if no time is specified, at the time of acceptance thereof as determined by the Chairman of the Board. Any Trustee may be removed by a majority vote of the Trustees at any meeting at which a quorum is present and the trustee is given reasonable prior notice of the potential removal.

Section 9. Vacancies

Any vacancies that may occur on the Board by reason of death, resignation, or otherwise may be filled by vote of the remaining members of the Board for the unexpired term.

Section 10. Indemnification

As used in this Article, any word or words defined in code of section 2-418 of the Corporations and Associations Article of the Annotated Code Of Maryland, as amended from time to time, (the ''Indemnification Section'') shall have the same meaning as provided in the Indemnification Section.

The Association shall indemnify and advance the expenses to a director or officer, of the Association in connection with proceeding to the fullest extent permitted by and in accordance with this Indemnification Section. With respect to an employee or agent, other than director or officer of the Association, the Association may, as determined by the Board of Trustees of the Association, indemnify and advance expenses to such employees or agent in connection with proceedings to the extent permitted by and in accordance with the Indemnification Section.

VIII. OFFICERS

Section 1. Elections

The elective officers of this Association shall be active members of the Association and consist of a President, President-elect, Vice-President, and a Treasurer. These officers shall be elected annually by mail ballot within sixty (60) days after nominations have been certified by the House of Delegates. The results shall be reported to the Board of Trustees by a Board of Canvassers appointed by the President.

Section 2. Installation

Each officer shall take office upon installation and immediately enter upon the performance of duties and shall serve for a term of one year or until the successor is duly elected and installed.

Section 3. Vacancies

Except for vacancies in the Position of President which will be filled by the Vice President and Speaker of the House of Delegates which will be filled by the Vice Speaker, vacancies in all other offices may be filled for the balance of the term thereof by a vote of the Board of Trustees at any regular or special meeting.

Section 4. President

The President shall be the principal elective officer of the organization and shall preside at membership meetings of the Association. In the absence of the Chairman of the Board of Trustees, the President shall preside at meetings of the Board of Trustees and of the Executive Committee. The President shall be a member ex-officio, of all committees with right to vote, and shall submit report at the Annual Meeting of the Association.

Section 5. Vice President

The Vice President may be delegated by the President to perform duties, in the event of the President's temporary disability or absence from meetings, and shall have such other duties as the President of the Board of Trustees may assign.

Section 6. President-Elect

The President-Elect shall have such duties as the President and the Board of Trustees may assign and serves in an ex-officio capacity on all committees.

Section 7. Treasurer

The Treasurer shall keep an account of all monies received and expended for the use of the Association, and shall oversee disbursements authorized by the Board of Trustees. All sums received shall be deposited in the institutions approved by the Board of Trustees. Funds may be drawn only upon the signature of the Treasurer and one or more other individuals approved by the Board of Trustees. The funds, books, and vouchers under the Treasurer's control shall, at all times, be subject to verification and inspection by the Board of Trustees.

Section 8. Executive Director and Staff

The administration and management of the Association shall be salaried staff head, employed or appointed by, and directly responsible to the Board of Trustees. This person shall have the title of Executive Director. The Executive Director shall be the chief executive and operating officer of the Association, with responsibility for the management and direction of all operations, programs, activities, and affairs of the Association, including employment and termination of employment of members of the staff and supporting personnel, functioning within the framework of policy aims and programs as generally determined by the Board of Trustees. The Executive Director shall have such other duties as may be prescribed by the Board. The Executive Director shall also be the Secretary to the Board of Trustees, and the Secretary to the House of Delegates. It shall be the duty of the Executive Director to give notice of and attend all meetings of the Association, to keep a record of all proceedings, to attest documents and perform such other duties as are usual for such official or as may be duly assigned.

Section 9. Bonding

At the direction of the Board of Trustees, any officer or employee of the Association shall furnish, at the expense of the Association, a fidelity bond, in such a sum as the Board shall prescribe.

IX. House of Delegates (House)

Section 1. Composition

The House of Delegates shall consist of the officers of the House of Delegates, Delegates of Record, and appointed Delegates at Large.

Section 2. Delegates of Record

Delegates of Record are delegates from recognized organizations, affiliated organizations and ex-officio delegates.

Section 3. Affiliated Organizations

An affiliated organization is a pharmacy organization which has entered into an affiliation agreement with the Board of Trustees. There must be a substantial cross-membership in both the affiliated organization and the Maryland Pharmacists Association. Four Delegates of Record are allocated for each affiliated organization for a full one year term.

Section 4. Recognized Organizations

A recognized organization is that pharmacy organization, the majority of members of which are pharmacists and which carried on activities designed to encourage and promote public health and advancement of pharmacy. Such organizations may be designated by the Board of Trustees. Tahe designation may be terminated by the House of Delegates. Two Delegates of Record are allocated for each recognized organization for a full one year term.

Section 5. Ex-Officio Delegates

The Officers, Trustees, and five immediate Past Presidents of the Maryland Pharmacists Association inclusive of Board of Trustees Members, and the Officers of the House of Delegate shall be eligible to serve as Ex-Officio Delegates with vote in the House of Delegates.

Section 6. Delegates at Large

The Speaker of the House of Delegates shall appoint twenty (20) delegates for each meeting of the House of Delegates with the approval of the Board of Trustees upon the petition by an active member to the Speaker to be considered for such appointment. Selection of Delegates at Large will be in proportion to the application received from each county. These delegates will serve for one meeting, but may be reappointed upon request by the delegates.

Section 7. Duties of House of Delegates

The House of Delegates shall be charged with the following duties and responsibilities: serve as the policy-making body of the Association; consider and implement by resolution, motion or other manner all appropriate proposals emanating from the membership; receive reports of Association Officers and Committees; adopt rules for the conduct of business; ratify the slate of officers and trustees for election and appointments to the Board of Pharmacy; and approve all proposed bylaws changes prior to a mail ballot.

Section 8. Election or Appointment of Delegates

Delegates shall be active members of the Maryland Pharmacists Association. They shall be appointed or elected by each affiliated or recognized organization for a period of one year. Delegates-at-Large shall be appointed by the Speaker of the House with the approval of the Board of Trustees for each meeting of the House of Delegates. Each organization may select as many alternate delegates as deemed practical, but they must be designated first alternate, second alternate, etc. All Delegates must be certified by the Secretary of the House at least thirty days prior to each meeting.

Section 9. Officers of House of Delegates

Officers of the House of Delegates will consist of the Speaker, Vice-Speaker and the Secretary. The Executive Director of the Maryland Pharmacists Association shall serve as Secretary.

Section 10. General Duties of the Officers of The House

The Officers of the House of Delegates shall arrange the programs for all meetings of the House of Delegates. The Officers shall represent the House of Delegates on the Board of Trustees and Association Committees to insure the dissemination of information and implementation of policies adopted by the House.

Section 11. Duties of the Speaker of the House

The Speaker of the House shall preside at all meetings of the House of Delegates, unless unavailable, at which time, the Vice Speaker will preside. In the event both the Speaker and Vice-Speaker are unable to preside, a temporary Speaker shall be elected by the House of Delegates. The Speaker shall appoint a parliamentarian to serve as an advisor on procedures and rulings. The Speaker shall appoint a Committee on Nominations, a committee on Resolutions and other committees of the House as may be necessary. The Speaker shall present an annual report for the House of Delegates.

Section 12. Duties of the Vice-Speaker of the House

The Vice-Speaker shall preside at meetings of the House of Delegates when the Speaker is unavailable. The Vice-Speaker shall serve as Chairman of the Resolutions Committee. The Vice Speaker will assume the duties of the Speaker in the event that the Speaker cannot fulfill the duties of that office.

Section 13. Duties of the Secretary of the House

The Secretary of the House shall read all relevant communications to the House. The secretary shall conduct and record voting in the House of Delegates when requested by the Speaker. The Secretary shall notify Committee members of the House of Delegates of their appointment and shall report and verify the credentials of all Delegates for House of Delegates sessions. The Secretary shall be responsible for the publication and maintenance of proceedings of the House of Delegates and shall distribute relevant reports to Delegates and interest parties in advance of the meetings of the House of Delegate to the extent possible.

Section 14. Meetings of the House

The House of Delegates shall meet at least twice yearly; once at the Annual Meeting and once at the Mid Year Meeting. Special Meetings of the House may be called at the discretion of the Speaker, with the consent of the Board of Trustees or upon written request of one-quarter of the certified Delegates of Record. The Secretary shall report and certify the Delegates who shall compose the House of Delegates. Each Delegate shall be entitled to one vote. No Delegate shall act as a proxy for another Delegate, nor as a Delegate for more than one (1) organization. All Association members may attend any session of the House of Delegates and shall be granted the privileges of the floor.

Section 15. Quorum

A quorum for purposes of conducting the business of the House shall be at least Twenty-five (25) Delegates and at least one Officer of the House.

Section 16. Resolutions

Resolutions may be submitted to the Resolutions Committee any time prior to the last meeting of the Committee which proceeds the Annual Meeting. In addition, Resolutions bearing the signature of two active members may be presented to the Speaker or Secretary of the House of Delegates at least 24 hours prior to consideration by the House.

The Resolutions Committee shall be appointed by the Speaker of the House of Delegates at least forty-five (45) days prior to the Annual Meeting of the Association. The Resolutions Committee shall be chaired by the Vice Speaker of the House of Delegates and in the absence or incapacity of the Vice Speaker of the House of Delegates another individual appointed by the Speaker of the House to serve as Chairman of the Resolution Committee. The Resolutions Committee will submit all resolutions to the Board of Trustees for its approval at least one (1) regularly scheduled meeting prior to the presentation to the House of Delegates.

Resolutions may be adopted by the House of Delegates, defeated, tabled or referred to a committee.

Section 17. Election of the Speaker and Vice Speaker of the House of Delegates

The Committee on Nominations shall be responsible for the nomination of candidates for the offices of Speaker and Vice-Speaker of the House of Delegates. The Committee on Nominations will present a slate of at least two candidates, if possible, for each position to a session of the House of Delegates at the Annual Meeting and, if approved by the House, an election will be held at the final session of the House at which the new officers of the House will be installed. The term of office for the Speaker and Vice Speaker is one year.

Section 18. Order of Business and Rules of Order

The Order of Business of the House of Delegates shall be developed by the Officers of the House. The Rules of Order of the House shall be the version of "Roberts Rules of Order" approved by the Board of Trustees.

X. COMMITTEE

Section 1. Presidential Appointments.

The President shall annually appoint such standing, special or subcommittees as may be required by the bylaws or as the President may find necessary.

Section 2. Executive Committee.

The Chairman of the Board of Trustees, the President, Vice President, President-Elect, Treasurer, Speaker of the House of Delegates and Executive Director (in an ex officio capacity) shall constitute an Executive Committee. They may exercise the powers of the Board of Trustees when the Board of Trustees is not in session, reporting to the Board of Trustees any action taken. Four (4) members shall constitute a quorum for the transaction of business. A meeting may be called by the Chairman of the Board of Trustees or the President.

Section 3. Nominating Committee

By at least three (3) months prior to the Meeting of the House of Delegates, the President, subject to the approval of the Board of Trustees, shall appoint a Nominating Committee of at least three (3) members in good standing to nominate two (2) individuals (if possible) for each forthcoming available Trustee seat on the Board of Trustees and each office except President and Chairman of the Board. Only one (1) candidate will be nominated for Honorary President of the Association.

In addition, the Nominating Committee will annually nominate three pharmacists for each of the forthcoming available pharmacist's seat(s) on the State of Maryland Board of Pharmacy. These nominations shall be reviewed and approved by the Board of Trustees and the House of Delegates before being submitted to the Secretary of the Department of Health and Menatl Hygiene for consideration by the Governor of the State of Maryland for appointment to the Board of Pharmacy. At least two (2) members of the Nominating Committee must be either a current officer or member of the Board of Trustees or Past President of the Association. Members of the Nominating Committee may not be nominated for any position.

Section 4. Finance and Budget Committee

The Finance and Budget Committee shall consist of the Treasurer as Chairman, the Chairman of the Board of Trustees, the President, the President-elect and up to two (2) additional members in good standing. A proposed annual budget of the Association will be prepared by the Finance Committee and presented to the Board of Trustees at least three (3) months prior to the beginning to the fiscal year. Simultaneous with the preparation of the budget, the Finance Committee will conduct a salary review of the Executive Director and if appropriate, will negotiate changes in the Executive Director's salary and benefits for presentation to and approval of the Board of Trustees.

XI. NOMINATIONS AND VOTING

Section 1. Nominating Process

The Nominating Committee shall be responsible for the selection and submission to the Board of Trustees the names of candidates for the offices of the Association as set forth in Article VIII Section 1 and Article VII, Section 3 of these by-laws.

Section 2. Slate Approval

After certification by the Board of Trustees, the slate of candidates will be presented to the House of Delegates for final approval. Further nominations for each such office may be made by the House of Delegates.

Section 3. Balloting

A ballot shall be submitted to the active membership by mail within sixty (60) days after the nominations for officers have been approved by the House of Delegates. The Officers and Trustees shall be elected from the persons whose names are printed on said official ballots, the nominee for each position receiving the highest vote as certified by the Board of Canvassers to be declared duly elected. In the event of a tie vote, a supplemental mail ballot election shall be held.

Section 4. Installation

Installation of all newly elected officers of the Association will take place at the Annual Meeting.

Continued from page 8.

Cole and deans Noel Foss and William J. Kinnard, Jr. This month, she will begin working three days a week in the Alumni/Public Affairs Office. A school luncheon was held at the University Club on December 7th to honor Margaret and 62 faculty and staff attended.

While 1988 marked Margaret Beatty's 40th anniversary, it also was Dr. Shangraw's 30th and Dean Kinnard's 20th year with the school.

Upcoming school events:

February 5—Alumni Association monthly meeting at 8:30 p.m. in Pharmacy Hall, Room 740

February 12—School/Alumni Association Valentine Party honoring Dr. Kinnard for his 20 years as Dean of the School of Pharmacy—2 p.m. in Pharmacy Hall Student Lounge.

February 19—Black graduates meeting at 2 p.m. in Pharmacy Hall, Room 740

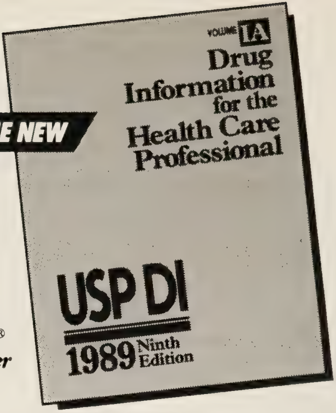
March 1—Alumni Association monthly meeting

March 18—Recruitment Open House for prospective pharmacy school students—program and tours begins at 9 a.m. in Pharmacy Hall Student Lounge—pre-registration required.

April 5—Alumni Association monthly meeting

April 10—University of Maryland Breakfast in Anaheim at the APhA convention. All Maryland pharmacists, alumni, students, faculty and friends are invited to attend. Cost is $12 for a full breakfast.

If you have any questions about any of these events, contact the University of Maryland School of Pharmacy Alumni/Public Affairs Office at (301) 328-5893.



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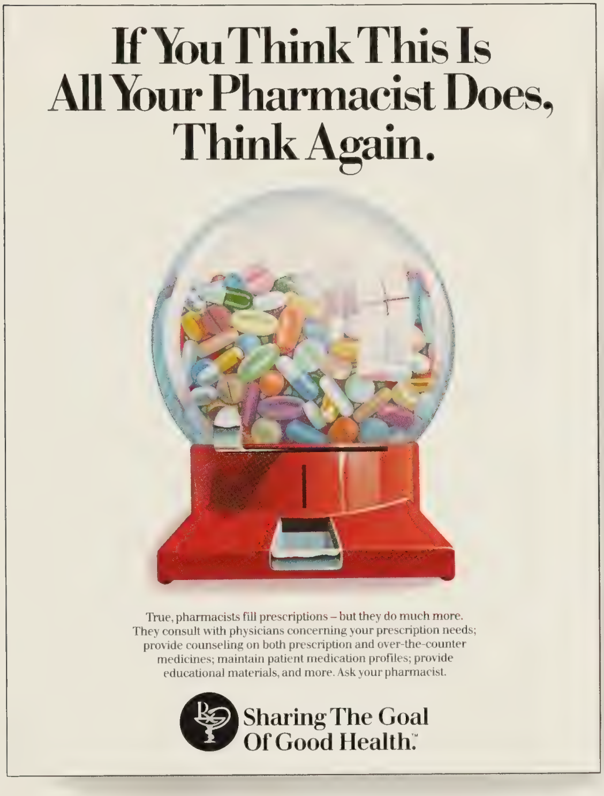

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We would appreciate receiving your comments. What subjects should we address in future posters? If you would like reprints of this poster, or others in the series, write to Upjohn Professional and Trade Relations, P.O. Box 30091, Lansing, MI 48909

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This and That About Pharmacy

Leon Weiner, P.D.

PHARMACY CHANGES—OCTOBER 1988

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Solomons, MD 20688

Thirft Drug #7341
Dorchester Square
Cambridge, MD 21613

Twin Knolls Pharmacy
8492 Baltimore Ntl. Pike
Suite 101
Ellicott City, MD 21043

Dart Drug #159
9185 Central Avenue
Capital Heights, MD 20743

Mallinckrodt, Inc.
5024-C Campbell Boulevard
Baltimore, MD 21236

Kaiswer Permenente
Camp Springs
6104 Old Branch Avenue
Temple Hills, MD 20748

Pharmacies Closed

Ocean Drugs
2114 Philadelphia Avenue
Ocean City, MD 21842

New Ownership and Name

Sappe's Morrell Park Pharmacy
2526 Washington Boulevard
Baltimore, MD 21230

New Name

Infusion Care, Inc.
6935-C Oakland Mill Road
Columbia, MD 21045
(Formerly Foster Medical Corp. Infusion Care)

NEWS BRIEFS. . . .

Maria Maggenti ('88) and William J. McCarthy, Jr., an attorney, were married recently. She is a pharmacist at Saint Joseph Hospital Pharmacy.

Joseph Anthony Ramos will graduate from the Philadelphia College of Pharmacy in 1989. He is the son of Oscar R. Ramos ('60—PCP). Oscar, the owner of Galena Pharmacy in Kent County, has worked in many of the pharmacies in Chestertown.

The City Paper Fifth Annual Best of Baltimore printed September 16, 1988 picked the following:

Best Milkshake Alpert's Pharmacy, 801 Park Avenue
Best Lunch Counter Medical Arts Pharmacy, 816 Cathedral St.
Best Uptown Lunch Counter Charlesmead Pharmacy, 6242 Bellona Ave.

Dr. and Mrs. Fred Magaziner have announced the engagement of their daughter Amy Ruth to James Richard Andersen, son of Mr. and Mrs. Charles Andersen. Fred ('54) is also a dental school graduate. An April wedding is planned.

Dr. and Mrs. H. Gerald Oster have announced the wedding of their daughter Joyce to Jason Mitchell Shapiro, son of Mr. and Mrs. George Shapiro of Aberdeen, NJ. Jerry ('58) is also a medical school graduate.

Mr. and Mrs. Ronald Dubansky of Frostburg have announced the marriage of his daughter Rachel Dora to Kevin L. Schene. Ron ('67) is a former Rite Aid pharmacist.

CONGRATULATIONS. . . .

To: Donald Dagold ('55) and wife Audrey on the engagement of their daughter Amy Ellen to Brad Glaser. Don, who owns Watermont Pharmacy, is the father of four girls.

To: Gail Rosen ('80) who was named Hospital Pharmacist of the Year at the recent MSHP Annual Convention in October. This award, sponsored by Pfizer Pharmaceuticals, recognizes a deserving pharmacist for noteworthy contributions made to the profession. Gail is currently Director of Nutritional Support Services at University of Maryland Medical System.

To: William Satisky ('55) and his wife Myra on the marriage of their daughter Janene Karen to Michael Siegel on July 9, 1988. Mike is the son of Harold Siegel ('57) and wife Harriet. Harold is the former owner of Fenwick Pharmacy in Baltimore and Willy is employed by Dart Drug.

To: William Satisky ('55) and his wife Myra, again, on the birth of their first grandson Eric Michael Satisky. Parents are Daniel ('81) and Terry Satisky. Dan works for MacGillivray's Pharmacy.

RECENT PASSINGS. . . .

Samuel F. Higger ('24) passed away on September 6, 1988 at his home in Washington. Sam, 84, operated a pharmacy in Baltimore before moving to Washington and opening Higger's Pharmacy in 1930. In 1960, Mr. Higger designed the pharmacy department at Sibley Memorial Hospital and managed it on a contract basis until 1963 when he retired. He was a member of Woodmont Country Club and the International Wine and Food Society.

Sister Louise Boswell, D.C. a retired hospital pharmacist passed away on November 2, 1988 in Emmitsburg. She retired in 1961 after 10 years with St. Mary's Hospital in Saginaw, Michigan. From 1926 until 1951, she worked at what is now Scared Heart Hospital in Cumberland. Prior to that, Sister Louise worked from 1920 until 1926 at St. Mary's Hospital in Detroit. The former Evelyn Marie Boswell was born in Brandywine in southern Maryland. She was a graduate of the Cass Technical School in Detroit. Sister Louise died after a long illness at Villa St. Michael, the Emmitsburg retirement home of the Daughters of Charity of St. Vincent de Paul.

Francis A. Davis, Jr. retired president of the F.A. Davis and Sons, Inc. passed away November 6, 1988 at his home in Towson. Mr. Davis, 63, retired in 1985 and sold his company. His business distributed tobacco products, sundries and other goods to many of the pharmacies in the Baltimore area. In 1948, Mr. Davis went to work for the company that his great-grandfather had founded. He started in a division that bottled Canada Dry products and eventually became president of the company in 1980.

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The Shearson Lehman Hutton retirement programs and packages are endorsed by the Maryland Pharmacists Association for its members. Both Myles and Jerry will be happy to help you plan for your future.

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889-7915
Proj. Dir.: Betsy Close

Allen Center for Sr. Citizens
Allen Center Board, Inc.
112 East West Street 21230
685-6224
Proj. Dir.: Jane Doble

Forest Park Senior Center
Forest Park Senior Center, Inc.
4801 Liberty Heights Ave. 21207
466-2124
Proj. Dir.: Josephine Lythcott

Govans Senior Center
Community Council of Govans
5225 York Road 21212
323-3576
Proj. Dir.: vacant

Harford Center for Senior Citizens, Inc.
4920 Harford Road 21214
Mail: P.O. Box 3534
426-4009
Proj. Dir.: Bernhard Kiewe

Hatton Senior Center
2825 Fait Avenue 21224
396-9025
Proj. Dir.: Hannelies Penner

Jewish Community Center/Older Adult Services
5700 Park Heights Ave. 21215
542-4900
Proj. Dir.: Peter Merles

Joseph Center for Senior Citizens
Associated Catholic Charities, Inc.
430 South Broadway 21231
732-5000
Proj. Dir.: Barbara Pearce

Korean Senior Center
Korean Social Services of Greater Baltimore
27 East North Avenue 21202
752-0166
Proj. Dir.: Chang Bae

Northwest Senior Center, Inc.
6776 Reisterstown Road 21215
Suite 201
358-6856
Proj. Dir.: Barbara Scher

Southwest Senior Center
Communities Organized to Improve Life
100 South Calhoun Street 21223
566-1311
Proj. Dir.: Betty Townsend

Waxter Center for Senior Citizens
861 Park Avenue 21201
396-1324
Director: C. Dwight Sutton

S.A.G.A. Centers (*S*ecurity and *A*ction for *G*olden *A*gers)
Headquarters:
Urban Services Agency—SAGA
2330 St. Paul Street 21218
396-7153
Proj. Dir.: Ulysta Evans

Oliver SAGA Center
1400 East Federal Street 21213
396-3861
Coordinator: Diana Samuels

Rosemont SAGA Center
730 Ashburton St. 21216
396-0340
Coordinator: Margaret Young

Greenmount West SAGA Center
1634 Guilford Avenue 21202
396-5160
Coordinator: Gloria Baywell

USA-West SAGA Center
1114 North Mount Street 21217
396-7724
Coordinator: Gladys Patterson

MPhA's Office Manager Beverly Litsinger has accepted a new position with the American Urologic Association. Congratulations and best wishes from Maryland pharmacy.

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Nasalcrom inhalers are now available in a 26 mls assembeled pump. Fisons has also announced that the 13 mls refill size will be discontinued.

William Edmondson, vice-president for government affairs of Glaxo, Inc. receives a plaque from PEP director Marvin Oed at a recent banquet for pharmacy school preceptors.

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Continuing Education

Continuing Education Quiz

The Maryland Pharmacist JANUARY, 1989

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by April 1, 1989. A continuing education certificate for one contact Photo #4 Caption

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Is this program used to meet your mandatory CE? [ ] Yes [ ] No

Did this article achieve its stated objectives? [ ] Yes [ ] No

How long did it take you to complete the program? __________ minutes

OTC Pregnancy Tests

1. OTC urine pregnancy testing products detect which of the following substances?
   a. Chorionic gonadotropin
   b. Estrogen
   c. Luteinizing hormone
   d. Progesterone

2. After a fertilized ovum becomes implanted in the endometrial wall, measurable amounts of the substance referred to in question #1 can be found in the urine approximately:
   a. 24 hours later.
   b. 72 hours later.
   c. 9 days later.
   d. 28 days later.

3. The best time to collect a urine sample for OTC pregnancy or ovulation testing is:
   a. after a 4-hour fast.
   b. early in the morning.
   c. midday, after the second voiding.
   d. just prior to going to bed.

4. Basal metabolic temperature measurement to predict ovulation is based on a:
   a. rise in resting body temperature that occurs one day before the surge in LH release from the pituitary.
   b. reduction of resting body temperature that occurs one day before the surge of hormone release from the pituitary.
   c. rise in resting body temperature that occurs one day after the surge of LH release from the pituitary.
   d. reduction in resting body temperature that occurs one day after the surge of LH release from the pituitary.

5. Which of the following trade names applies to both a pregnancy test and an ovulation test?
   a. Advance
   b. Clearblue
   c. Answer Plus
   d. First Response

6. If a urine sample cannot be used for pregnancy testing immediately after voiding, it should be:
   a. stored in a refrigerator.
   b. kept at room temperature.
   c. frozen and thawed out later.
   d. discarded.

7. OTC urine ovulation testing products detect which of the following substances?
   a. Chorionic gonadotropin
   b. Estrogen
   c. Luteinizing hormone
   d. Progesterone

8. The pregnancy tests that are reportedly more accurate employ:
   a. monoclonal antibodies
   b. polyclonal antibodies

9. The phenothiazine derivative that has been reported to cause a false negative response with first generation pregnancy tests is:
   a. Thorazine
   b. Mellaril
   c. Phenergan
   d. Stelazine

10. The hormone that makes the endometrial lining more receptive to implantation of a fertilized ovum is:
    a. chorionic gonadotropin.
    b. estrogen.
    c. luteinizing hormone.
    d. progesterone.

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

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January 15—AZO Sunday Breakfast
January 18–25—MPhA Trip to Aruba
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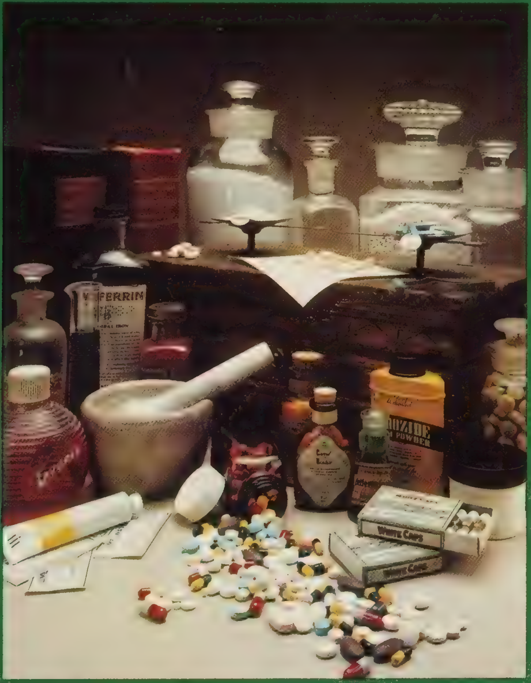
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Commentary

A MID-YEAR PRESIDENTIAL PROGRESS REPORT

When I took office in June, 1989, I recognized various problems facing the Maryland pharmacy profession: third party programs, doctor dispensing for profit, continuing education, and the role and regulation of pharmacy supportive personnel.

The first immediate problem was the Blue Cross auditing program. When alerted by our members, we took immediate action. We did what you anticipated and expected by protecting pharmacists from unreasonable demands by third-party programs that impinge on our professional practice.

Our next concern was the unilateral slashing of reimbursement by Prudential Insurance Company and PCS for Baltimore City employees. Again, your association was there to provide communication to all pharmacists about the problem, and to explain to Prudential, PCS, and union and city officials why this change was unacceptable.

Doctor dispensing for profit is now being handled by a very capable legislative committee. For the first time, MPhA and the leaders of the Maryland Chain Drug Store Association are sitting together and agreeing on methods of eliminating this very serious threat. We will not allow the health care of the citizens of Maryland to be jeopardized by this unethical practice.

Under the capable leadership of Ilene Zuckerman, our House Speaker and chairman of the Technician Task Force, a survey was conducted to help direct our association in addressing this issue. The results of that survey will be published shortly in *The Maryland Pharmacist*.

Nathaniel Futeral, president elect and chairman of the Legislative Committee has once again distinguished himself. Our legislative breakfast on January 25, 1989 brought out the Governor, Lieutenant Governor, and more than 25 delegates and senators. Representatives from MPhA visited every senator and delegate's office to encourage them to use the association as a vital and reliable source of information about pharmacy and medical concerns.

Our Survival Fund is well on its way and our goal of $100,000 must be met. Please link your name to the many members who have contributed. It's not too late to do your part.

It's been an exciting six months and I am hoping that my next six months as president of this fine organization will be as productive.

Elwin Alpern, P.D.

President

The Art of Patient Counseling

Correspondence Course

The Art of Patient Counseling

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. illustrate how pharmacists can communicate better with their patients; and
2. present specific examples of communication errors and suggest how they can be avoided.

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Objectives

At the completion of this lesson, participants will be able to:

1. identify specific reasons why pharmacist/patient communication is important;
2. select correct interpretations of commonly used terms;
3. choose from a list, specific duties which studies have shown that pharmacists should perform as part of their professional responsibilities; and
4. identify specific barriers and other influences that interfere with good communication.

One-half of all Americans take their medication incorrectly. They take it at the wrong time, in the wrong dosage, or take it concurrently with other drugs that interact.

Reports have demonstrated that patients expect personal attention and professional services from the pharmacist. Popular magazines and pharmaceutical association notices encourage the public to consult a pharmacist about their drug questions. Many physicians, and even the FDA, are advising Americans to establish a good rapport with a pharmacist.

This article examines pharmacist/patient communication. It illustrates the level of communication that currently exists, and offers suggestions for improvement.

Pharmacists Talk to Their Patients

Pharmacists may have convinced themselves that they do communicate drug information to their patients. Most pharmacists talk to their patrons. They often begin an encounter with, "Hi, how are you?" or "May I help you?" Then, while completing the transaction they may inquire about the patient's family, or comment about the weather, sporting events or the world political turmoil. As they hand over the prescription, perhaps encased in a paper bag, they announce the price and indicate that "Your doctor says you should take one tablet stat, then three times a day. Call me if you have any questions about your script. And thank you for your business."

True indeed! The pharmacist talked to the patient and communicated his appreciation for shopping the pharmacy. But throughout the encounter, how much actual communicating of health-related information actually transpired? Did the patient truely understand what his medication was for? Did he understand what "stat" and "three times a day" meant? And what about OTC products or food or alcoholic beverage interactions? The patient may not think about these questions until he is ready to take his medication.

The 1975 Millis Commission Report indicated that pharmacists of the future will function as transmitters of information. The Commission reported that ". . .the greatest failing of pharmacy is its inadequacy as an information transmitting system." It urged pharmacists to command principles of communication and use them because future pharmacists will dispense more information than medication. Unfortunately, studies have shown that as little as 5 to 6 percent of pharmacists' time is actually spent in consulting with patients.

Unconvinced that American consumers want more personal consultation and information? Then browse the shelves of any bookstore. Dozens of books have been written for the lay public that deal with various topics in health, including books that give specific information on prescription and OTC drug items. In fact, the *Physician's Desk Reference* (PDR) is one of the most popular books purchased by consumers and consulted in libraries across the country. It has appeared in the "Top 10" list of best sellers numerous times.

The pharmacy literature stresses that good pharmacist/patient communication is paramount to professional practice today. Speakers at professional meetings also encourage good communication.

This information may be misleading to pharmacists who are interested in promoting communication. Communication specialists often assume that pharmacists can spend unlimited cash to hire others to perform many of the duties that will give them time to communicate, or to rearrange the pharmacy layout and purchase necessary furnishings. They also assume that pharmacists have time to attend college classes to learn basic communication skills, or, that they can start the first day to communicate effectively with all their patients. This lesson presumes none of these.

Make the Commitment

Fast or Slow? There are two theories on how fast a communication program can be initiated. The first states that it is best to jump right in and counsel everyone. An advantage is that most mistakes will be made early on and pharmacists should benefit from extensive practice.

The other opinion stresses that pharmacists should begin slowly. Aristotle said ". . .you learn to play the flute by playing the flute!" In other words, pharmacists should try counseling a limited number of patients on the first day and maintain this schedule until they feel comfortable to expand. Or, they can concentrate at first on patients who receive certain types of medication, such as birth control regimens, antibiotics, or ingrown toenail remedies. Once mastered, the number of patients can be increased each day until all who need counseling receive it.

Move Buffers and Barriers. Pharmacists' work areas have evolved around numerous barriers to good communication. Clerks represent one of the greatest barriers. A clerk assigned to the prescription receiving area may be the only person the patient encounters. The clerk meets and greets the patient, transmits the prescription to the pharmacist, then often returns the medication to the patient who then questions the clerk about the prescription. The clerk may respond and the pharmacist is never involved in the counseling process. Unfortunately, neither patient nor clerk knows what questions or information are pertinent. The pharmacist then is actually dispensing to the clerk.

The prescription countertop is another barrier. This is typically a 4 to 5 feet high, 2 to 3 feet deep structure that very effectively shields the pharmacist from his patients. It is frequently topped with promotional displays or lined along the rear with fast moving prescription items and a backlog of third-party record forms and remnants of yesterday's lunch. The poor patient just doesn't have a chance to communicate in this setting.

Then too, a raised platform behind this counter may elevate the pharmacist. Such elevations permit pharmacists to observe store activities and certainly raises them to positions of authority. But this subconsciously intimidates patients so they do not feel comfortable communicating on a one-to-one basis. So the setting for poor communication is further fostered.

Table 1 lists other barriers that interfere with open and effective communication. Many are obvious; others may not be. They should be identified and removed. Usually little or no expense is involved. Wholesaler merchandise can often be received in another section of the pharmacy or kept out of sight until it can be put away. Seasonal display units that require floor space can be moved away from the pharmacy area. All other displays, signs, and objects that may distract a patient during communication should also be moved.

Merchandise and displays can be removed from the top of the prescription counter. And better yet, pharmacists can come out from behind the counter and stand at eye level with their patients to communicate with them.

Clerks can be instructed to receive and transmit a patient's prescriptions, but the medications should be dispensed directly by the pharmacist. This same clerk can engage in conversation with other patients who are waiting, to help temper their anxiety from having to wait for the pharmacist. More importantly, this makes the person with whom the pharmacist is currently serving feel more relaxed. High anxiety is correlated with low recall. Clerks should be instructed to answer all questions that do not relate to drugs or disease. The clerk's answer may be inadequate, incomplete, or even incorrect! Such questions should only be answered by the pharmacist.

Make the Time. Moving barriers and clearing the aisles are easy. Finding the extra time to spend in counseling patients is another matter. An average patient counseling session should not require more than 1 to 2 minutes. But this time, multiplied by the number of patients needing it, adds up.

First, time is not found. It is made! Appoint another person to handle nonprofessional chores such as routine mail opening, stocking and

Table 1

Common Barriers to Pharmacist-Patient Communication

- High counters and pharmacy counter clerks
- Language barrier and ethnic differences
- PPIs, books, auxiliary labels and printed directions sheets
- Poor pharmacy layout; noisy or active waiting area
- Merchandise on floor or countertops that distract patients
- Other patients waiting who may overhear
- Age differences (i.e., young pharmacist in a community of older persons)

dusting, checking in orders, building displays and answering the telephone. Even responsibilities such as completing third-party forms and price changing can be delegated to a trusted clerk. Professional journals and reading material can be taken home to study.

Ask a pharmacist colleague to spend a few hours observing you and recommend specific areas where a change in operation will produce significant time savings. Maybe you can return the favor to them or to another colleague.

Set definite goals for each day and prioritize them. List them on a 3x5 card, and keep it in view throughout the day, and proceed according to this schedule. Time efficiency experts claim that many minutes will be added to each working day by having activities planned in advance. These added minutes can then be devoted to patient counseling.

Many pharmacy journal advertisements and other printed pieces contain diagrams, figures and pictures that make excellent reference material for patient counseling use. Start a filing system for such information and keep it current. Use this to demonstrate specific points to a patient. A description of how gastric acid secretion is halted by an H_2 blocker, for example, or how to correctly brush and floss the teeth will be more easily understood, and longer retained, when such illustrations are used.

The total time needed with each patient may be decreased by not having to verbalize some of the concepts. Only material that is easily understood and figures that are clear should be used. Extraneous words and artwork can distract the patient's attention, confuse him, and require the pharmacist to spend more time than necessary to explain what it all means.

Clear off the prescription counter work area. If there is not a separate office area or desk, set aside an unused portion of the prescription counter to serve this function. Separate it from the area devoted to prescription activities. Do not waste time repeatedly searching for items that are usually covered beneath piles of papers, advertising copy, books, order forms and other collectables. Items that aren't used each day should be moved elsewhere, out of the way. More precious minutes are thus gained.

Table 2

OPEN ENDED. Good way to open conversation. Example: "What other medication are you taking?" Questions cannot be answered yes or no.
CLOSE ENDED. Answered yes or no. Best to avoid since patient is forced into one of two answers.
DIRECT. Use when more specific information is needed. Example: "You mentioned that the directions were not clear. Which specific part is not clear?"
SUGGESTIVE. Questions suggest that something should or should not happen. Example: "This drug causes sedation. Did you feel tired?" Should be avoided unless they are the only means to get the patient started talking.
REFLECTIVE. Questions begin by commenting on the last few words of patient's statement. If patient remarks that "These tablets made me feel nauseous," then a reflective question could begin, "You feel nauseous . . . ?" Question then would bring out more detailed information. People may feel positive about this type of questioning since it shows the pharmacist is really listening to them.

Frequently dispensed medications should be brought closer to the work area. Log all movements into each bay or shelf area for a couple days. Decide which items need to be moved closer to the counter, then move them.

Schedule Patient Visits. Many days have periods that are busier than others. During these rushed times, counseling patients may be especially difficult. The following suggestion isn't appropriate for every patient, but it will work for some.

First, keep an accurate record of prescription filling activity during each 30 minute segment for the next 2 to 3 weeks. Record the number of prescriptions filled and indicate whether they are new or refills. A definite pattern of activity should emerge. Then, suggest to selected individuals who normally bring in refills during these busy periods that they may wish to come at another time. Or, ask them to call in their refill prescription number(s) in advance. When they do come in, you can spend more time discussing their health questions and drugs.

In one survey of pharmacy patients, 70 percent admitted that if the pharmacist looked extremely busy, they would not bother him with questions. And the majority indicated that unless more pressing circumstances prevailed, they would gladly come to the pharmacy when the pharmacist was not as busy.

Say it Correctly

Health professionals communicate through a common language that is understood by other health practitioners. But it may mean little or nothing to a patient. Imagine a patient casually being told to take a "stat" dose of medication, or to take it "pc!" Pharmacists casually tell their patients that "The 'sig' on your script is. . ." and so on. Even medical terminology such as pediculosis, tinnitus, hyperkalemia or hypertension may confuse the patient.

But don't talk down to patients either. Use terms they can understand. Start by putting them at ease and tell them you are interested in making sure they fully understand the directions.

Learn to communicate the ideas you want stressed and to elicit the specific information you need from a patient. To avoid misunderstanding and minimize incorrect or incomplete information being given, refer to the questioning techniques in Table 2.

Label Instructions

Instructions on the label are also open for misinterpretation. Prescription labels that otherwise seem clear to both pharmacist and patient at the time of dispensing may be confusing at the time of administration. A study illustrated this point.

Outpatients in a clinic pharmacy were asked to interpret the labels on each of ten prescriptions. The labels contained commonly used phrases. For a prescription for propoxyphene HCl, for example, patients were instructed to "Take one capsule every four hours as needed for pain". They were encouraged to question the pharmacist to help clarify the direc-

PRESCRIPTIONS
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tions. Questions relating to effectiveness, side effects, refills, drug interactions and other warnings and precautions were asked. But no one asked what "as needed" meant.

The patients were then asked to assume they took a capsule at 8 a.m. If pain were still present at 10 a.m., could another dose be taken? Approximately 20 percent responded affirmatively. In fact, when they were asked to state how many capsules could be taken each day, about half responded incorrectly with answers ranging from two to eight.

In another investigation, patients were asked to interpret the meaning of a label affixed to their antihypertensive medication which stated, "This prescription cannot be refilled." Seven percent believed it meant that the medication did not need to be taken any longer.

Similar confusion in label instructions still exists for some OTC products. For example, one young girl believed that the contraceptive jelly she purchased was to be spread on her breakfast toast. Months later when she learned otherwise, she also discovered why she had become a mother.

Pharmacists should not assume that patients understand even the most simple terminology. In fact, the major reason people do not take their medication correctly is that they do not understand the directions. The pharmacist should explain the directions for prescription items and OTC medications, and use language that the patient understands. They should then ask that this information be repeated by the patient in his own words.

Nonverbal Communication

The unspoken word is often more suggestive than the spoken. People judge others by the visual impressions they leave. It was shown in one study that only 5 percent of an overall message is conveyed by the spoken word, 55 percent is transmitted by the tone and facial expressions, and 40 percent by body language.

Pharmacists who display a perpetually bewildered look, or always refer to a book or microfiche before answering a question, or constantly clear their throat before talking or keep their head bowed with eyes directed to the floor while talking, may give the impression that they do not know what they're doing. Even small gestures such as furrowing the brow or scratching the head while studying the prescription may send negative vibrations to the patient.

Overview

Communication skills are developed through practice. Not all patients need counseling, but many do. Pharmacists can practice good communication on just a few patients at first and then expand.

Pharmacists should identify unnecessary barriers around the pharmacy and remove them. They should also initiate drug information rather than wait to be asked. Pharmacists can let consumers know that they are ready to serve them by displaying such notices throughout the pharmacy. By using their imagination to discover more ways to improve communication skills, everyone will benefit.

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Women In Pharmacy

A new, independent nationwide survey reports that women are vaulting to a majority position in pharmacy and have already attained equal recognition and equal rewards in the profession.

"Twenty-eight percent of licensed pharmacists are women, and they account for about 60 percent of all students in colleges of pharmacy," said Dr. Jack Robbins, director-pharmacy affairs, Schering Laboratories. "Considering the growing presence of women in pharmacy, looking to the future, we are talking about at least a three-to-two ratio in favor of women, and the study suggests that this ratio may grow even larger."

Schering Report X, "A Profession in Transition: The Changing Face of Pharmacy," probes the nature and consequences of the ascendancy of women in pharmacy against a background where pharmacists are reexamining and reevaluating their choice of career, educational preparation and day-to-day working conditions. The report also explores how pharmacists view their compensation, work practices and environment, and their evolving role as "physicians' surrogates" in selecting generic drugs, counseling consumers on minor ailments and recommending over-the-counter medications.

In the 1988 study, nearly 400 pharmacists from every corner of the country—in small and large, rural and urban communities—were interviewed in depth. They included representatives from chain, independent and hospital pharmacies as well as health maintenance organizations (HMOs).

The growing presence of women in pharmacy points to women pharmacists outnumbering their male counterparts in the future, the study indicated. Given the relatively recent entrance of women in large numbers in pharmacy, it's no surprise that those already out of school and on the job tend to be younger. The average age of women pharmacists is 32, compared with 42 for men. To underscore the dynamics of their future impact on the profession, women pharmacists, while comprising 28 percent of all pharmacists, account for only 12 percent of pharmacists over age 40 but 57 percent of the under-30 segment.

Where are these mostly younger women pharmacists working? Women represent 40 percent of pharmacy personnel in hospitals, 34 percent in chains and 19 percent in independents. As for being part of management, only 36 percent have advanced to owner/manager status.

But a different picture emerges in narrowing the focus to pharmacists who entered the profession in the last five years. Here, 25 percent of women pharmacists are in management ranks, the same proportion as men who also started working in the same period. Obviously, these women are not being denied their fair share of promotions.

There is no reason to believe that, as women pass through the seniority pipeline, they won't gain management status at the same rate as men. Women already have achieved respect as heads of retail and hospital pharmacies. Whether women will achieve statistical parity with men as owners of independent pharmacies will, in large part, be their own decision.

When women do become managers, 75 percent have other pharmacists reporting to them, the exact same percentage as for men. How many reportees? 2.1 for male managers and 2.3 for women. Also, there was little if any difference in the size of the organizations women choose to work in. The numbers of total employees and of pharmacists were virtually identical.

On careers and children three out of 10 women took time off from their careers to be mothers, with those over 40 more likely than their younger counterparts to have exercised the option. In most cases, the sabbatical lasted less than a year.

Just how well do women pharmacists fare in compensation? Looking at all men and all women who had started work in the last 10 years, women—at average annual earnings of $36,100—are paid the equivalent of 90 cents for every dollar earned by men, who have average annual salaries of $40,200.

The study pointed out, however, that these women pharmacists, presumably by their own choice, clock in a 9 percent shorter workweek than men—42 hours compared with 46 hours. On the basis of hours worked, men are paid $16.80 an hour, with women earning slightly less at $16.52, "statistically not a significant difference . . . pointing out that contributions of both men and women pharmacists are equally recognized and equally rewarded."

With so many career opportunities available, why did the pharmacists choose pharmacy as a profession? The most prevalent influence relates to family—either a pharmacist in the family or family encouragement—or some early exposure, such as part-time work in a pharmacy while in school. These influences were especially strong in the case of independent pharmacy owners. For hospital pharmacists, an early interest in science or chemistry was a major motivator.

What about the next generation? When pharmacists were asked if they were anxious to pass their mortars and pestles down to their children, by a three-to-two majority they said, "Yes, indeed, I would want my son or daughter to be a pharmacist."

Citing what may be a harbinger of future trends, the study noted that several pharmacists said they would recommend a pharmacy career for their daughters, but not for their sons.

In listing "career opportunity" as the leading attraction of a pharmacy career, the advocates cited relatively good job security and "always lots" of job openings, and, especially for women, flexible working hours. Professional rewards, including both challenge and self-satisfaction, were also high on the list of factors, and fully one in four pharmacists saw financial rewards for their children as career benefits.

Of pharmacists who said "no" to pharmacy for their offspring, 38 percent cited poor working conditions, including "long hours, no lunch, no breaks, stress, bad hours, and working weekends and holidays."

On the down side of financial rewards, 17 percent of the pharmacists said "salaries don't rise with experience and ability. Starting out you can do well, but you don't make much progress."

What do pharmacists earn? Based on the Schering Report, the average salary for all pharmacists is $39,000 a year, with the majority (52 percent) earning between $35,000 and $45,000. Independent pharmacy owners, reaping the rewards of entrepreneurship, report annual earnings of $46,000. The $36,700 average salary for employee pharmacists reveal little variation among chains, independents and hospitals.

Looking back at how well pharmacy schools prepared their charges for careers, 27 percent of pharmacists said their school did an "excellent" job, 45 percent said "very good," followed by 20 percent "good," 7 percent "fair" and 1 percent "poor."

The number of years since graduation appeared to affect the evaluations. Only 65 percent of those who graduated over 20 years ago said "excellent," compared with 85 percent who got their degrees within the past five years. Women were more approving in their rating (79 percent) than men (69 percent).

One reason for the greater satisfaction of younger pharmacists with their education might be their likelihood of having been in externship programs. They mentioned this factor twice as frequently as their elders. Among the reason for their schools' unfavorable ratings, pharmacists often cited the lack of adequate training for the business end of pharmacy, or the lack of practical training.

These themes arose again when pharmacists were asked how pharmacy education could be improved. More business courses, including accounting, bookkeeping and computers, said 40 percent of those questioned, with older pharmacists expressing strong needs and independent pharmacy owners advocating the loudest for business training.

The Schering Report also looked at the pharmacist's typical workweek. The 40-hour workweek is a reality for only one pharmacist in three. Overall, the average

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workweek runs 45.2 hours, small consolation to the 36 percent who work upwards of 46 hours, with an industrious—some label them burnout material—11 percent clocking 60 hours or more.

Where a pharmacist works and the job level also counts. Employees clock the shortest week, averaging about 39 hours at hospitals and independents, and 41 hours in chains. A full two-thirds of hospital employee pharmacists punch out for the week with 40 or fewer hours.

The other side of the picture is the workweek of managers and owners, many of whom evidence severe symptoms of workaholism. Overall, they toil an average 48.6 hours a week, but the prize for most-dedicated workaholic goes hands down to the independent owner at 54.3 hours.

The workweek of women pharmacists averages about the same, around 40 or 41 hours, whether they work at chains, independent or hospitals. Men, however, average 44 or 45 hours at chains and hospitals but stretch to 49 hours at independents.

The differences between the male and female workweek may be abating. This is suggested by the fact that younger women pharmacists put in 42 hours weekly, compared with only 37 hours for those with over 10 years' experience.

Among the pharmacists' myriad weekly duties, which do they enjoy most? Their two top favorites were dealing with patients (either in person or by phone) and filling prescriptions, followed by contact with physicians and their staff. Pharmacists obviously recognize that, beyond the clinical and scientific aspects, pharmacy is essentially a person-to-person experience, he added. Their job demands that they be skilled in communicating with both patients and physicians.

Underscoring the person-to-person nature of the pharmacist's job, more than 50 percent said they liked supervising employees, perceiving this activity as a rewarding part of the job.

What pharmacists disliked most were completing third-party claim forms, general cleanup, keeping billing records, maintaining shelf stock and talking with sales representatives. Everyone complains about the rising tide of paperwork. Small wonder that so many managers are crying out for more and better business education, including computers, to tame the paperwork tiger before it eats us all alive.

How about break time to alleviate the pressure of a long, multifaceted work day? Not much—both employees and their managers seem to agree. Mealtime is a mere 19 minutes a day, with hospitals pharmacists enjoying an average 33 minutes, compared to 18 at independents and 11.5 at chains.

Coffee breaks follow a similar pattern among the three types of outlets. Hospital pharmacists get the most time, about 21 minutes, compared with an average six minutes for all pharmacists. Many pharmacies have no policy for breaks. In fact, 56 percent of chains and 36 percent of independent managements say they give no time for meal breaks, whereas virtually all hospitals do. The coffee break is even rarer, having no place in 73 percent of chains and 57 percent of independents.

How pharmacists perceive working conditions in the three types of outlets bears directly on where they choose to work, the study noted. Independents are clear-cut favorites, lauded for their more-relaxed environment and their high level of patient contacts.

Hospital pharmacies were strong runners-up. They are perceived as having less onerous working conditions and a more professional and better-organized environment that, at the same time, is more relaxed.

Pharmacists gave chain pharmacies a net negative rating—more bottom than top scores—pointing to intense pressure and generally poor working conditions. The dubious distinction of being thought by pharmacists as having the worst working conditions belongs to HMOs and supermarket chain pharmacies.

Among other pharmacists, there is a strong feeling that HMOs offer little direct contact with patients and are loaded down with rigid routine, the report noted. The disdain by many for supermarket chain pharmacies is prompted by the proximity of bread and butter and bananas, creating an ''unprofessional'' environment. There is also an aversion to reporting to a non-professional, presumably the supermarket manager.

Because figuring out what supervisors want, and then delivering it, is central to job success, the Schering Report probed what pharmacy owners and managers expect from their employees and how well employees perceived the relative importance of qualities sought by their supervisors.

continued on Page 14. . . .

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Topping the list of most highly prized traits by managers is work habits—competence, efficiency, promptness, dependability, reliability and, of course, plain hard work. Then came ethics, personal characteristics, customer-oriented communications skills, knowledge, potential for advancement and finally—somewhat of a surprise—experience.

Employee rankings were not too different, the survey indicated, with work habits at the top of the list and experience in last place. The greatest shortfall showed up for "potential for advancement." Only about half as many employees as managers feel this is an important characteristic to demonstrate on the job. Many employees seriously understate the importance of showing that they have initiative and are willing and able to take on greater responsibilities, including managing other employees.

Clocking over 50 conversations a day with patients, pharmacists—by an overwhelming 83 percent—believe the public has a positive image of pharmacists. Yet, half of those interviewed believe that there is still more to do in promoting the pharmacist's image. Specifically, they believe the public needs to be better informed about their educational accomplishments and the various types of questions they're qualifed to answer.

Those who feel enough is already being done point to the increase in pharmaceutical-company-sponsored advertising recommending that people "ask their pharmacist." Several noted that advertising and promotion emphasizing price rather than service acts to diminish the image of pharmacists in the eyes of the public.

Assuming there is always room for improvement, who gets the job of promoting the image of pharmacy? National, state or county pharmacy associations? Colleges of pharmacy? Pharmaceutical companies?

Among the three types of associations, pharmacists viewed national associations as doing the best job. Colleges of pharmacy were respectable runners-up, and a solid 50 percent said that, as a whole, pharmaceutical companies are making a commendable effort in supporting the profession.

Noting that pharmacists filled over 1.5 billion prescriptions last year, the Schering Report asked how they select a particular brand of product for a prescription. Thirty percent said the key factor is the reputation of the company or the product; 28 percent reported that the decision was made by others, for example, the company buyer or the patient's preferences; 18 percent noted they were bound by a formulary; 16 percent said they use the product available at the cheapest price; and 13 percent replied that they use the product already in stock.

On average, retail pharmacists engage in 20 face-to-face conversations with patients every day that are not just about filling prescriptions. Rather, the pharmacist is responding to requests for advice on minor ailments and which brand of over-the-counter (OTC) medication to buy for those ailments.

What's the No. 1 health complaint for which patients seek their pharmacist's advice? Coughs and colds head the list, followed by sinus problems, aches and pains, allergies, headaches, constipation, ear aches, fever, athlete's foot, strains and sprains, and pre-menstrual syndrome.

Because most of these ailments are of the now-you-have-it, now-you-don't variety, many people don't want to spend the money or the time to consult a doctor. They turn instead to the professional often perceived as the physician's surrogate—the local pharmacist.

What factors influence a pharmacist in recommending a particular OTC brand? The No. 1 reason is simply that the brand has proved to be effective for other patients, the pharmacists reported. Then came satisfactory personal experience, the reputation of the brand and of the company, and the fact that the OTC product was formerly a prescription product.

Schering Report X pointed out many significant differences between independents, chains and hospitals; between men and women; between younger and older pharmacists; and between management and employees. Above all, it revealed that there are more attributes that unite pharmacy than divide it. What unites pharmacy, above all, is a dedication to identify areas where we can all improve and grow together.

A booklet summarizing the Schering study is available by writing: Pharmacy Affairs Department, Schering Laboratories, Kenilworth, N.J., 07033.

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MD

Dickinson's Pharmacy

by Jim Dickinson

Pharmacists are too cheap! "Let's face it, we pharmacists are *cheap!*" confessed a New Yorker in the front row. The group was discussing whether independent pharmacy has a future, and how much it might cost to rescue it.

The accusation pleased me. I've never had a free prescription from a pharmacist, but I'm frequently asked by pharmacists for a free newsletter or other editorial product (if you keep reading, you'll find out how to get another one!).

There's an old saying to the effect that you don't value what comes free or cheap. Pharmacy association dues are a fraction of others (e.g., journalists pay $360–$565 to the National Press Club, pharmacists $110 to APhA).

This may mean peril to the profession. Since most of pharmacy's reading matter is free, it also may not be valued, and thus the profession may not be arming itself with the knowledge needed to defend the traditional values of the profession and its survival.

In short, if you don't shoot back in this war, you should expect to be killed, professionally speaking. ("*It's not actually making me bleed right now, and maybe it won't, ever—so why buy bullets?*")

Recent new developments suggest that pharmacists will not have a lot of time to buy ammunition and fight back, even if they want to.

The new Medicare drug benefit, for example, begins in 1992, and it is already being infiltrated by mail-order interests (despite statutory language that ambiguously seems to require counseling but which is being bureaucratically circumvented).

Like HMOs, other private carriers and self-insured employers, Medicare is afraid that the drug benefit will be too expensive. And there has been a backlash against Medicare's published drug coverage premiums, co-pays and other costs. Something will have to give.

Even those with the most deeply-held convictions against the inflexible, impersonal nature of mail-order drugs, are finding themselves forced to consider this mechanism on cost grounds alone.

Who is dissuading them?

Frankly, they hear a babble of opposing voices, each shouting pieces of a message that is too complex to be quickly grasped. Some of the individual pharmacists who write letters and get on the phone are self-defeatingly emotional.

I recently tried to talk an HMO benefits controller out of mandatory mail-order for all oral contraceptives. She was both sympathetic to the principle of face-to-face pharmacy and skeptical of any possible patient hazards in the mail-order alternative.

Such arguments as secondary monitoring for lifestyle changes in the case of drugs with narrow therapeutic thresholds and the risks of polypharmacy were over her head. Her world is dollars and cents.

The behavior of some pharmacists tends to encourage this perception. They don't routinely counsel or keep their patient profiles current, and they get active in policy issues only when hit in the wallet.

Unfortunately, these pharmacists seem to the ones that HMO benefits administrators patronize exclusively, for their own needs.

Getting the order, largely unheard side of pharmacy's story across is fundamentally difficult, and made next to impossible by the bottom-line myopia of the health cost containment crisis.

That's what is so important about December's call by RxNet, the national PSAO, for a $50-per-pharmacy injection of operating funds.

RxNet is the one great hope that community, face-to-face pharmacy has to get a sophisticated, effective story across, in terms that go beyond the bottom line cost of the drug commodity.

Working on a shoe-string, always too slowly (it was afraid to ask for more than $25 start-up dues from its participating pharmacies!), RxNet now has established the first national electronic data processing "switch" for all pharmacy claims transactions.

The importance of this can't be overstated, in a market that is quickly being locked into arbitrary systems configurations by the onrush of the Medicare drug benefit.

Will those systems allow all pharmacies equal access to the future? Can Medicare and other plans be educated about the value of the care that community pharmacy can provide, and its cost-effectiveness?

Who will make that effort for pharmacy, if it's not RxNet and its network of state PSAOs (most of which, incidentally, are also starved for resources by dues that are generally way too low)?

Do I hear you muttering, "what have they done for me lately?" To find out, send me your name and address to receive a free copy of my latest *Dickinson's PSAO* newsletter (P.O. Box 848, Morgantown, WV 26507-0848).

But first, please rush $50 to RxNet at 205 Daingerfield Road, Alexandria, VA 22314.

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Administer cautiously to allergic patients

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it
- Prolonged use may result in overgrowth of nonsusceptible organisms
- Positive direct Coombs' tests have been reported during treatment with cephalosporins
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include

- Gastrointestinal (mostly diarrhea), 2.5%
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] and toxic epidermal necrolysis or the above skin manifestations accompanied by arthritis/arthralgia, and frequently, fever): 1.5%, usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely
- Rarely, reversible hyperactivity, nervousness, insomnia, confusion hypertonia, dizziness, and somnolence have been reported
- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1% and, rarely, thrombocytopenia

Abnormalities in laboratory results of uncertain etiology

- Slight elevations in hepatic enzymes
- Transient fluctuations in leukocyte count (especially in infants and children)
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- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinitest® tablets but not with Tes-Tape® (glucose enzymatic test strip, Lilly). [061088]

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Backgrounder: Aids-Related Kaposi's Sarcoma (KS)

A skin disorder once rarely seen in the United States, Kaposi's sarcoma (KS) is now the most common malignancy associated with acquired immune deficiency syndrome (AIDS). According to the Centers for Disease Control (CDC), of the 78,312 individuals who have been diagnosed with AIDS since 1981, almost 10%—7,078—have KS. It is unclear why KS occurs at such a high rate in AIDS patients or why KS is found particularly in homosexual and bisexual men with AIDS rather than in AIDS patients from other risk groups. Although opportunistic infections, such as *Pneumocystis carcinii* pneumonia, cytomegalovirus, and cryptococcal meningitis, are the major cause of death in AIDS patients, the development of KS contributes significantly to the morbidity of these patients. (1)

KS was first recognized in 1872 by Moritz Kaposi, who reported it as a "multiple pigmented sarcoma" of unknown origin that seemed to occur predominantly in older men. (2) Sarcoma refers to a malignant tissue growth arising in bone, muscle, or other connective tissue. Physicians now know that KS is a rare tumor that can arise in many different areas of the body and represents a proliferation of abnormal, apparently cancerous, blood vessels. KS frequently first presents as enlarged lymph nodes and red-purple to blue-brown lesions of the skin and other organs. The lesions, which commonly erupt on the lower extremities, hands, ears, and nose, may be firm or compressible, solitary or numerous, and may appear initially as a dusky stain, especially on the toes. Irrespective of their location, the lesions are usually painless. (3)

Prior to the recognition of AIDS-related KS, it had been thought of primarily as a rare disease occurring in Europe and North America among elderly men of Jewish or Mediterranean ancestry. This form of the disease, refered to as classic KS, usually is manifested as slow growing lesions confined to the skin of the lower limbs. (4) Classic KS normally progresses with a slow, chronic course and rarely causes death. (5) Men, usually in their 70s, are affected 10 to 15 times more often than women and have an average survival time of approximately 10 years, although some live much longer. The incidence of this form of KS is less than 0.1 per 100,00 population and constitutes fewer than 0.02% of all malignancies. Classic KS also has been known to occur in organ transplant recipients, whose immune function is weakened.

In 1950, a unique form of KS was discovered in black children and young black men in tropical Africa. (6) Here, the disease is endemic and accounts for 3% to 9% of all malignancies. This form of KS is more destructive within tissues, is distributed over a considerably greater area of the body than classic KS, and has a rapidly fatal course. Involvement of the visceral organs (internal organs, especially the abdomen), rather than of the skin, and disease of the lymph nodes are the predominant clinical signs. Most patients are younger than 20 years old and survive less than three years. (2)

KS in AIDS Patients

Since 1979, an aggressive, extensively disseminated form of KS, often involving the lymph nodes and viscera and showing a rapidly fatal course, has been reported in North America and Europe among patients with AIDS. Those affected are usually young, male homosexuals with a mean age in the fourth decade.

In AIDS patients, the disease is, to some extent, similar to the disseminated African form, and it is characterized by several features that distinguish it from classic KS. For one, the cancer takes a rapid, aggressive form and follows a significantly different pattern from that seen in classic KS. (7) The skin lesions of AIDS patients with KS tend to be smaller, softer, flatter, lighter in color and more widespread and generalized in distribution than the firm lesions of the legs found in classic KS. In non-AIDS-related KS there is a 10% incidence of extracutaneous involvement—involvement of organs other than the skin—and in the KS observed in African children and young adults there is a 20% incidence of extracutaneous involvement. In contrast, in AIDS-related KS, extracutaneous involvement exceeds 70%. (2)

In classic KS the most commonly involved organs are the lymph nodes and gastrointestinal tract, whereas virtually any organ system can be affected in the AIDS-related, disseminated form. (2) In AIDS-related KS, tumors can invade the gastrointestinal tract, lymph nodes, lungs, or retroperitoneum (the area behind the membrane lining the abdominopelvic wall) and cause substantial morbidity and death. In addition, mucous membrane tumors or lesions of the viscera or lung often may appear before the skin lesions. Finally, in contrast to classic KS, which rarely causes death, the average survival time for AIDS-related KS from onset of the disease is less than two years. (2)

Possible Etiology

While AIDS is strongly believed to be caused by a retrovirus referred to as human immunodeficiency virus (HIV), the cause of KS is unknown. However, the connection between KS and other malignancies and opportunistic infections has implicated reduced immune competence, infectious agents, and genetic and environmental factors as playing a role in acquiring KS. (2) Circumstantial evidence has suggested a possible association between another virus, cytomegalovirus, and both classic and AIDS-related KS. (8)

Most Treatments for KS Found Ineffective

Although there is currently no curative treatment for the underlying immune defects of AIDS, investigators have attempted to treat AIDS-related KS with irradiation, chemotherapy and certain immunomodulators. Although chemotherapeutic agents can induce responses in some patients with classic KS, treatment of AIDS-related KS with anticancer drugs is limited because of the considerable toxicity associated with the drugs. Additionally, anticancer drugs tend to suppress bone marrow and thus further depress the patient's immune function. This would be a potentially dangerous side effect in AIDS patients, as it increases risk for infections to which these patients are susceptible.

Recombinant Alpha Interferon Shows Promise for AIDS-Related KS

For the last six years, recombinant interferon alfa-2b ('Intron A') and other alpha interferons have been studied as a therapeutic agent for patients with AIDS. (9) Studies have now indicated that recombinant interferon is clearly an active agent for the treatment of AIDS-related KS. In a series of clinical trials, response rates have ranged from 20% to 67%. (10)

In initial trials, therapy with 'Intron A,' a highly purified, genetically derived alpha-2b interferon, resulted in sustained regression or elimination of KS lesions in one-third to one-half of patients treated. KS patients who had not lost significant amounts of weight or developed sustained fevers seemed to have a particularly good response rate. These responses also were associated with prolonged survival and a lower incidence of opportunistic infections. Moreover, interferon therapy did not produce the severe toxicities commonly seen with the conventional chemotherapy used against KS.

More Extensive Trials Confirm Early Work

Studies with a larger number of AIDS patients with KS have now confirmed that 'Intron A' can induce remissions of long duration. (11,12) In these clinical trials, which formed the basis for the FDA's approval, patients received 'Intron A' in one of three dose levels. The FDA approval is for subcutaneous and intramuscular use. Thirty-one patients received an intravenously injected high dose of 50 million units of interferon per square meter of body surface; 65 patients received a subcutaneously injected dose of 30 million units per square meter of body surface three times weekly; and 29 patients received a subcutaneously injected daily dose of 35 million units per square meter of body surface.

Clinical responses were observed with all three regimens. Patients were considered to have a complete response when all lesions had completely disappeared or flattened and a partial response if one half of the lesions had completely flattened or disappeared and no new lesions had appeared. In all regimens, patients with a less compromised immune system at entry to the study (as assessed by T4 lymphocyte counts) were more likely to respond to therapy. Similarly, asymptomatic patients (those with no fevers or weight loss) were more likely to respond to treatment than patients with symptoms. At the 50 million IU dose, 57% of asymptomatic patients responded versus 23% of symptomatic patients; at the 30 million IU dose, 47% of asymptomatic patients responded versus 9% of symptomatic patients.

Patients who responded to treatment lived significantly longer than nonresponders (median survival 23 months vs 10 months). 'Intron A' was generally well-tolerated, although most patients experienced flu-like symptoms, including fever, chill, and fatigue. In these studies, only six patients (6%) discontinued treatment because of adverse reactions.

The clinical responses produced by all three regimens confirm the previously reported activity of alpha interferon against AIDS-related KS. (10,13)

Alpha Interferon May Have Direct Effects Against the AIDS Virus

In AIDS-related KS, recombinant alpha interferon may work by directly inhibiting the rapid multiplication of cells, as well as by modulating the immune system. *In vitro* and early clinical results also suggest that alpha interferon might be directly affecting the HIV virus.

In a clinical study conducted by Dr. Clifford Lane at the National Institute of Allergy and Infectious Diseases, encouraging antiviral results were observed in AIDS patients with KS treated with 'Intron A'. (12) This study not only confirmed prior studies demonstrating the high rate of tumor regression produced by interferon in KS patients but also suggested that inteferon may have an additional role as a direct antiviral agent.

Importantly, in addition to showing anti-tumor responses, some patients also showed a persistent reduction in the ability to culture HIV from their blood. This, like the anti-tumor effects, appeared to correlate with the patient's degree of immune function upon entry to the study. These patients also had a marked reduction of a core viral protein, a marker for HIV.

This study indicates that in the future interferon by

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itself or in combination with other anti-AIDS drugs may play a significant role in the treatment of other AIDS patients. Such studies are now underway.

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Pharmacist John Conrad of Bel Air receives his Syntex "Preceptor of the Year" plaque from Wendy Williams, Syntex professional representative and Marvin Oed, director of PEP at the University of Maryland. Conrad is the owner of Bel Air Apothecary and his name will be placed on a plaque at the School of Pharmacy.

GLOSSARY

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS): A serious, fatal condition, caused by a retrovirus, in which the immune system becomes defective and is not able to fight infection. Individuals with AIDS commonly develop Kaposi's sarcoma, a cancer, or recurrent infections often caused by organisms that do not normally present a threat to healthy individuals (those with uncompromised immune function or systems).

AIDS: See Acquired Imune Deficiency Syndrome

AIDS-RELATED KAPOSI'S SARCOMA: A form of Kaposi's sarcoma seen in approximately 10% of all AIDS patients. This form of the cancer is generally fatal and very aggressive, invading the skin and other organs, such as the lungs, lymph nodes and gastrointestinal tract. *See* Kaposi's sarcoma, classic.

CLINICAL RESPONSE: Any positive response by a patient to therapy. The response can be either complete, in which all signs or symptoms of the disease improve, or partial, in which at least one half of the signs or symptoms of a disorder improve and no new signs appear.

CRYPTOCOCCAL MENINGITIS: An inflammation of the membranes surrounding the brain and spinal cord caused by *Cryptococcus*, a yeastlike microorganism. The infection often strikes patients with AIDS and is considered an opportunistic infection.

CYTOMEGALOVIRUS: One of a group of viruses that causes disease primarily in humans with impaired immune systems, such as those with AIDS and those being treated with immunosuppressive drugs.

T4 CELLS OR CD4 HELPER/INDUCER T CELLS: A class of lymphocytes (white blood cells) that play an integral role in the functioning of the immune system. Helper/inducer T cells are markedly depleted after infection with the AIDS virus (HIV).

HUMAN IMMUNODEFICIENCY VIRUS (HIV): Previously referred to as HTLV-III, HIV is a retrovirus of the human T cell leukemia/lymphoma virus family.

IMMUNOSUPPRESSIVE: Causing a lowering of the body's normal immune response. Patients with AIDS and those who have received specific drugs after organ transplantation are immunosuppressed.

'INTRON A': A highly purified, genetically derived alpha-2b interferon manufactured by Schering Corporation.

KAPOSI'S SARCOMA, CLASSIC: A generally nonfatal malignant cell growth that occurs primarily in elderly men of Jewish or Mediterranean ancestry and is manifested as slow-growing purplish lesions confined to the skin of the lower limbs. Classic KS differs in many ways from the Kaposi's sarcoma that afflicts patients with AIDS.

LESION: A general term for any visible, local abnormality in tissue, such as an injury, wound, boil, sore, or rash. Kaposi's sarcoma is characterized by purplish lesions of the lower legs. *See* Kaposi's sarcoma.

MONOCYTE: A type of lymphocyte (white blood cell) that ingests and destroys bacteia and other foreign particles.

OPPORTUNISTIC INFECTION: An infection caused by a microorganism that ordinarily does not cause disease in humans; it occurs in those whose immune systems are compromised, as, for example, those with AIDS or those receiving immunosuppressive drugs.

PNEUMOCYSTIS CARINII PNEUMONIA: A type of pneumonia caused by the parasite *Pneumocystis carinii* that usually occurs only in infants or those whose immune systems are compromised. It is the most common opportunistic infection associated with AIDS, afflicting more than one half of all AIDS patients.

RETROVIRUS: A virus that encodes its genetic information in ribonucleic acid (RNA) and uses a unique viral enzyme to copy its genetic information into DNA. This feature allows the virus to integrate and reproduce itself in human cells. AIDS is caused by a retrovirus (HIV).

SARCOMA: A tumor, often highly malignant, arising in bone, muscle, or connective tissue.

Drug Product Selection
A Professional Responsibility

In the early 1970's Maryland became one of the first states to allow the pharmacist the right to interchange brands of drug entities to make quality medication more affordable for patients. Led by Paul Freiman, Bernard Lachman and other active MPhA members, a law was enacted allowing the interchange of a very limited number of medications, mainly anti-biotics. Despite all out efforts from some areas to hamper the efforts of the pharmacist to become the "purchasing agent" for the public, the law was gradually changed until the current law was put into effect in the late 1970's allowing substantial savings and little or no therapeutic changes for the public.

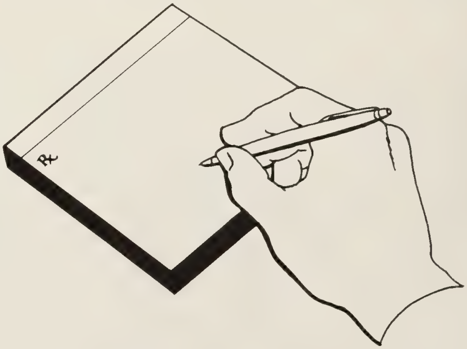
The Current Law

Along the way, a few problems developed, such as the problem of furosemide inequivalence. Maryland addressed this by allowing for emergency deletions from the list of interchangeable drugs. The use of generic phenytoin demonstrated that there are both immediate and slow release products and only the slow release products are bioequivalent and interchangeable with the Dilantin 100mg extended release capsules.

The current law allows the pharmacist to interchange products which are therapeutically equivalent, contain the same active ingredients, are identical in strength or concentration, dosage form (ie: capsule or tablet), route of administration, and salt or esther—provided that the physician does not prohibit interchange in his own handwriting. The patient must be notified in writing of any change of brand that was made. There must be a savings to the patient for the use of a generic equivalent product.

Insurance companies and other third-parties often require that generics be used and, in many cases, the pharmacist must resolve the requests of the patient and physician, the requirements of the law, and the rules of the payor. This may take the form of dispensing a brand because the physician prohibits substitution or the patient requests the brand, but having to charge the patient the difference between the generic and brand name price because the third-party will not pay for it.

Since it is nearly impossible for the practicing pharmacist to make his own determination of equivalency, the Maryland law mandates a Drug Formulary to be updated periodically by the Drug Formulary Committee and distributed to each pharmacy. The Formulary Committee is comprised of members of the scientific community and physician and pharmacist practitioners. The Committee is chaired by Paul Freiman and by Charles Tregoe. Listed by the name of manufacturer are the brands of generics which can be interchanged. Care must be taken to insure that the name of the manufacturer on the label is approved as interchangeable as many brands are marketed by distributors who are not manufacturers and whose names may not be listed in the formulary.



The Orange Book

The Maryland Formulary is based on the FDA list of *Approved Drug Products with Therapeutic Equivalence Evaluations* which is now in its eighth edition. The Maryland Formulary may vary from this list if the Formulary Committee determines that any particular product should not be considered bioequivalent.

The FDA book, commonly known as the Orange Book, lists all approved manufacturers of a generic entity with a two letter rating system. The first letter of the evaluation indicates if the product is considered therapeutically equivalent ("A") or not ("B"). The second letter provides additional information on the basis for FDA's evaluation. For example, "AA" drugs are equivalent and have met an appropriate *in vitro* test. "AB" drugs are equivalent and have submitted bioavailability or clinical data for approval. Other second letters, such as "O" (oil solutions), "P" (injectable aqueous solutions), "T" (topicals), explain what information or testing was required to obtain the first letter "A" rating.

Ratings beginning with "B" are drugs which have had equivalency problems reported and are not interchangeable. The drugs may be dispensed if written for, but cannot be substituted for another brand of the same drug without the prescriber's permission. When appropriate data is presented to FDA to show equivalence, the rating is changed. As example, controlled-release oral products are rated "BC" until bioavailability studies show bioequivalence. Then the rating is changed to "AB."

To complicate matters, there are some products that have special clarifications attached to their ratings. For example, erythromycin stearate tablets are coded "AB" for therapeutic equivalence *only if* taken on a fasting stomach. Theophylline tablets rated "AB" are equivalent for twice daily dosing but not for once a day dosing.

For those who use the Orange Book, the rating is to the left of each manufacturer's brand. Remember that while the Maryland Formulary is primarily based on this standard, there is a potential for changes and deviations. Maryland law allows interchange only if the product and manufacturer is listed in the Maryland Formulary.

Maryland Medicaid, some Blue Cross programs, and other third-parties use the Maryland Formulary as the basis for requiring generic substitution. Ms. Leone Marks of Maryland Medicaid points out the need to be very specific when substituting. Diprolene ointment, while containing the same active ingredient in the same strength as other betamethasone diproprionate ointments, including Diprosone ointment, is not bioequivalent and therefore should not be interchanged with these products. Hydrocortisone, neomycin sulfate and polymyxin B sulfate otic solutions and suspensions, including Cortisporin, are interchangeable as solutions *or* suspensions, but not interchangeable between solutions *and* suspensions.

Pharmacists who take the time to study the law as well as the Orange Book's preface will have the basic knowledge to easily provide quality approved generics to better serve the patient and the insurer.

NEW MEMBERSHIP BENEFIT

Working with the Mid Atlantic Food Dealers Association, the MPhA is pleased to announce a coupon redemption program designed for rapid turnover and easy administration. Pharmacists will receive the face value for all valid coupons submitted plus the following: batches of 500 coupons and under—$.02 per coupon; 500 to 1000 coupons—$.02.5 per coupon; and batches of 1000 coupons and over—$.03 each. This special Coupon Redemption program also helps the MPhA. The Food Dealers Association's has a very large Coupon Redemption program for its member grocery stores. Take advantage of the security, rapid turnover and outstanding reimbursement available to you for the first time.

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SAVE 20

Business Property: Individual vs Corporation

James R. Talley, M.S.
School of Pharmacy
Northeast Louisiana University
Monroe, Louisiana

The question of who should own business property, you as an individual or your corporation, is an important overall ingredient in the business strategy of your pharmacy operations. Depending on your specific circumstances, the correct decision may represent several thousands of dollars saved in taxes. This decision has been somehwat complicated by the Tax Reform Act of 1986 which changed the rules on real estate tax write-offs by making losses deductible only against "passive" rather than "earned" income.

Although IRS has tightened the rules, it still may be advantageous for you to place your pharmacy, warehouse, land, and building in your individual name rather than in your corporate name. By so doing, it may be possible to extract income from your pharmacy without having to pay corporate taxes on this amount. Thus, the rental incomes go directly to you as an individual and are free of corporate tax. By having income go to you, the individual owner, instead of to your corporation, may help avoid two tax traps.

First, this may reduce the amount of accumulated income and resultant tax penalties that may be levied on this corporate income by IRS. Second, by receiving individual income by property rentals may alleviate claims of "unreasonable compensation" by IRS in regard to the salary your corporation pays you from your pharmacy. In addition, individual ownership of property may provide a mechanism around passive loss regulations of IRS. It may also be possible for you as an individual property owner to shelter cash flow, even when passive losses cannot be deducted.

How to structure property ownership is an extremely complex situation which involves legal and financial considerations. You are advised to consult your tax attorney and/or CPA for specific details.

THEO-DUR
THEOPHYLLINE (Anhydrous)
Sustained Action Tablets

INDICATIONS THEO-DUR is indicated for relief and/or prevention of symptoms of asthma and for reversible bronchospasm associated with chronic bronchitis and emphysema
CONTRAINDICATIONS THEO-DUR is contraindicated in individuals who have shown hypersensitivity to theophylline or any of the tablet components
WARNINGS Status asthmaticus should be considered a medical emergency and is defined as that degree of bronchospasm which is not rapidly responsive to usual doses of conventional bronchodilators Optimal therapy for such patients frequently requires both *additional medication* parenterally administered, and *close monitoring*, preferably in an intensive care setting

Although increasing the dose of theophylline may bring about relief, such treatment may be associated with toxicity The likelihood of such toxicity developing increases significantly when the serum theophylline concentration exceeds 20 mcg/ml Therefore, determination of serum theophylline levels is recommended to assure maximal benefit without excessive risk

Serum levels above 20 mcg/ml are rarely found after appropriate administration of recommended doses However, in individuals in whom theophylline plasma clearance is reduced *for any reason*, even conventional doses may result in increased serum levels and potential toxicity Reduced theophylline clearance has been documented in the following readily identifiable groups 1) patients with impaired renal or liver function, 2) patients over 55 years of age, particularly males and those with chronic lung disease, 3) those with cardiac failure from any cause, 4) neonates, and 5) those patients taking certain drugs (macrolide antibiotics and cimetidine) Decreased clearance of theophylline may be associated with either influenza immunization or active infection with influenza

Reduction of dosage and laboratory monitoring is especially appropriate in the above individuals Less serious signs of theophylline toxicity (i e nausea and restlessness) may occur frequently when initiating therapy, but are usually transient, when such signs are persistent during maintenance therapy, they are often associated with serum concentrations above 20 mcg/ml Unfortunately, however, serious side effects such as ventricular arrhythmias, convulsions or even death may appear as the first sign of toxicity without any previous warning Stated differently *serious toxicity is not reliably preceded by less severe side effects*

Many patients who require theophylline may exhibit tachycardia due to their underlying disease process so that the cause/effect relationship to elevated serum theophylline concentrations may not be appreciated

Theophylline products may cause dysrhythmia and/or worsen pre-existing arrhythmias and any significant change in rate and/or rhythm warrants monitoring and further investigation

The occurrence of arrhythmias and sudden death (with histological evidence of necrosis of the myocardium) has been recorded in laboratory animals (minipigs, rodents and dogs) when theophylline and beta agonists were administered concomitantly, although not when either was administered alone. The significance of these findings when applied to human usage is currently unknown
PRECAUTIONS THEO-DUR TABLETS SHOULD NOT BE CHEWED OR CRUSHED
General Theophylline half-life is shorter in smokers than in non-smokers Therefore, smokers may require larger or more frequent doses Morphine and curare should be used with caution in patients with airway obstruction as they may suppress respiration and stimulate histamine release Alternative drugs should be used when possible Theophylline should not be administered concurrently with other xanthine medications Use with caution in patients with severe cardiac disease, severe hypoxemia, hypertension, hyperthyroidism, acute myocardial injury, cor pulmonale, congestive heart failure, liver disease, in the elderly (especially males) and in neonates In particular, great caution should be used in giving theophylline to patients with congestive heart failure Frequently, such patients have markedly prolonged theophylline serum levels with theophylline persisting in serum for long periods following discontinuation of the drug Individuals who are rapid metabolizers of theophylline, such as the young, smokers, and some non-smoking adults, may not be suitable candidates for once-daily dosing These individuals will generally need to be dosed at 12 hour or sometimes 8 hour intervals Such patients may exhibit symptoms of bronchospasm near the end of a dosing interval, or may have wider peak-to-trough differences than desired

Use theophylline cautiously in patients with history of peptic ulcer Theophylline may occasionally act as a local irritant to the G I tract although gastrointestinal symptoms are more commonly centrally mediated and associated with serum drug concentrations over 20 mcg/ml
Information for Patients The physician should reinforce the importance of taking only the prescribed dose and time interval between doses THEO-DUR tablets should not be chewed or crushed When dosing THEO-DUR on a once daily (q24h) basis, tablets should be taken whole and not split As with any controlled-release theophylline product, the patient should alert the physician if symptoms occur repeatedly, especially near the end of the dosing interval
DRUG INTERACTIONS Drug-Drug Toxic synergism with ephedrine has been documented and may occur with some other sympathomimetic bronchodilators In addition, the following drug interactions have been demonstrated

Drug	**Effect**
Theophylline with lithium carbonate	Increased excretion of lithium carbonate
Theophylline with propranolol	Antagonism of propranolol effect
Theophylline with cimetidine	Increased theophylline blood levels
Theophylline with troleandomycin, erythromycin	Increased theophylline blood levels

Drug-Food *THEO-DUR 100 mg Sustained Action Tablets* have not been adequately studied to determine whether their bioavailability is altered when given with food Available data suggest that drug administration at the time of food ingestion may influence the absorption characteristics of theophylline controlled-release products resulting in serum values different from those found after administration in the fasting state

A drug-food effect, if any, would likely have its greatest clinical significance when high theophylline serum levels are being maintained and/or when large single doses (greater than 13 mg/kg or 900 mg) of a controlled-release theophylline product are given

THEO-DUR (200, 300, and 450 mg) Sustained Action Tablets The rate and extent of absorption of theophylline from THEO-DUR 200 mg, 300 mg, and 450 mg tablets when administered fasting or immediately after a moderately high fat content breakfast is similar
Drug-Laboratory Test Interactions When plasma levels of theophylline are measured by spectrophotometric methods, coffee, tea, cola beverages, chocolate, and acetaminophen contribute falsely high values
Carcinogenesis, Mutagenesis, and Impairment of Fertility Long-term animal studies have not been performed to evaluate the carcinogenic potential mutagenic potential, or the effect on fertility of xanthine compounds
Pregnancy Category C—Animal reproduction studies have not been conducted with theophylline It is not known whether theophylline can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity Xanthines should be given to a pregnant woman only if clearly needed
Nursing Mothers It has been reported that theophylline distributes readily into breast milk and may cause adverse effects in the infant Caution must be used if prescribing xanthine to a mother who is nursing taking into account the risk-benefit of this therapy
Pediatric Use Safety and effectiveness of THEO-DUR administered
1 Every 24 hours in children under 12 years of age, have not been established
2 Every 12 hours in children under 6 years of age, have not been established
ADVERSE REACTIONS The most consistent adverse reactions are usually due to overdose and are
1 *Gastrointestinal* nausea, vomiting, epigastric pain, hematemesis, diarrhea
2 *Central nervous system* headaches, irritability, restlessness, insomnia, reflex hyperexcitability, muscle twitching clonic and tonic generalized convulsions
3 *Cardiovascular* palpitation, tachycardia, extrasystoles, flushing, hypotension, circulatory failure, ventricular arrhythmias
4 *Respiratory* tachypnea
5 *Renal* albuminuria, increased excretion of renal tubular and red blood cells, potentiation of diuresis
6 *Other* rash, hyperglycemia and inappropriate ADH syndrome
OVERDOSAGE Management If potential oral overdose is established and seizure has not occurred
A Induce vomiting
B Administer a cathartic (this is particularly important if sustained-release preparations have been taken)
C Administer activated charcoal
if patient is having a seizure
A Establish an airway
B Administer oxygen
C Treat the seizure with intravenous diazepam, 0 1 to 0 3 mg/kg up to 10 mg
D Monitor vital signs, maintain blood pressure and provide adequate hydration
Post Seizure Coma
A Maintain airway and oxygenation
B If a result of oral medication, follow above recommendations to prevent absorption of the drug, but intubation and lavage will have to be performed instead of inducing emesis, and the cathartic and charcoal will need to be introduced via a large bore gastric lavage tube
C Continue to provide full supportive care and adequate hydration while waiting for drug to be metabolized In general, the drug is metabolized sufficiently rapid so as not to warrant consideration of dialysis, however, if serum levels exceed 50 mcg/ml charcoal hemoperfusion may be indicated
CAUTION Federal law prohibits dispensing without prescription For full prescribing information see package insert
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Please see next page for brief summary of prescribing information

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Vice Speaker Murhl Flowers conducted the mid-year business session of the House of Delegates.

NEW DRUG UPDATE
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The Plight of the New Owner: Kathy Parker, owner of Arnold Professional Pharmacy, rests between CE sessions at the mid-year seminar. Congratulations to Kathy on her new pharmacy.

More than 160 pharmacists attended the February 5 Mid-Year Educational Seminar at the Annapolis Ramada Hotel.

A special welcome to pharmacist-to-be Maureen Wood and proud parents Greg and Barbara Wood. Born January 18, Maureen already has 5.5 credits for her license renewal in 2004.

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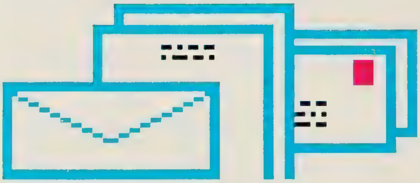
Writing Your Legislator

Communicating with your elected legislators is one of the most important contributions you can make to the political process. The U.S. Mail is an economical and effective way for you to communicate your views to elected officials at all levels of government — federal, state, county or local. Your representatives not only want your thoughts on important issues, they need your views and ideas to help them effectively represent you. Writing effective letters to your Senators and Representative is not a difficult task. Here are a few guidelines that will make writing to your representatives even easier.



UNITED STATES
The Honorable John Doe
United States Senate
Washington, DC 20515
Dear Senator Doe:

The Honorable John Doe
House of Representatives
Washington, DC 20515
Dear Representative Doe:

STATE
Maryland State Senate
James Senate Office Building
Annapolis, MD 21401-1991

Maryland House of Delegates
Lowe House Office Building
Annapolis, MD 21401-1991

- *Write on your personal or business stationery, if possible,* and sign your name over the typed signature at the end of your message.

- *Be sure that your return address is on your letter, not just on the envelope.* Envelopes sometimes get misplaced before the letter is answered.

- *Identify the subject of your letter clearly.* Give the name of the legislation you are writing about. Use the appropriate House and/or Senate bill numbers, if possible.

- *State your reason for writing.* Your own personal experience is your best supporting evidence. Explain how the legislation would affect your state or community.

- *Avoid trite phrases and sentences.* Cliches make your letter appear to be part of an organized "pressure" campaign — and, thus, minimize the impact of your message.

- *Be reasonable.* Don't ask for the impossible. Don't threaten. Don't say, "I'll never vote for you unless you..." That will not help your cause; it may harm it.

- *Be constructive.* If a bill deals with a problem that you admit exists but you believe that the bill takes the wrong approach toward solving that problem, explain what you believe the right approach is.

- *Don't pretend to wield vast political influence.* Write your representative as an individual, not as a self-appointed spokesman for your neighborhood, community or industry. Unsupported claims of political influence only cast doubt upon the views you express.

- *Don't become a constant "pen pal."* Quality, rather than quantity, is what counts. Don't try to instruct your legislators on every issue that comes up. And don't nag them if their votes do not reflect your thinking every time. Remember, each member has to consider all of his or her constituents and all of their points of view.

- *Ask your legislators to explain their position on the issue in reply.* As a constituent, you're entitled to know how and why they feel as they do.

- *Consider timing.* Try to communicate on a bill while it still is in committee. Your Senators and Representatives usually will be more responsive to your views at that time — rather than later on, when the bill has already been shaped by a committee.

- *Thank your representatives if they please you with a vote.* Everybody appreciates a complimentary letter — and remembers it. On the other hand, if they displease you, don't hesitate to communicate your displeasure — that, too, will be remembered.

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ATTENTION
MR. INDEPENDENT RETAILER

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1. IS YOUR CUSTOMER BASE ERODING DUE TO DEEP DISCOUNT COMPETITION?
2. ARE YOUR PRESCRIPTION CUSTOMERS BUYING THEIR HBA'S FROM YOUR COMPETITION? (CHAINS, MASS MERCHANDISERS, GROCERY STORES)
3. ARE YOUR HEALTH AND BEAUTY AIDS PRICES COMPETITIVE?
4. IF SO, ARE YOU TELLING YOUR CUSTOMERS?
5. HAS INCREASED THIRD PARTY PRESCRIPTIONS AND COMPETITION AFFECTED YOUR PRESCRIPTION DEPARTMENT PROFIT?
6. ARE YOU TIRED AND CONFUSED FROM SEARCHING FOR THE BEST SOURCE OF SUPPLY, AT THE BEST PRICE, TO FILL YOUR O.T.C. AND PHARMACEUTICAL NEEDS?
7. ARE YOU INTERESTED IN A TOTAL PROGRAM THAT WILL SOLVE ANY OR ALL OF THE ABOVE?

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Continuing Education Quiz

The Maryland Pharmacist FEBRUARY, 1989

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Is this program used to meet your mandatory CE? [ ] Yes [ ] No

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Art of Patient Counseling

1. All of the following are true about patient counseling EXCEPT:
   a. every patient receiving a prescription needs counseling.
   b. the average patient counseling session should not require more than 1 to 2 minutes.
   c. talking to a patient from a raised platform may produce poorer patient compliance.
   d. high patient anxiety is related to poor learning and recall.

2. According to information in this article, which of the following is a major reason people do not take their medication correctly?
   a. Consumer-oriented books explain directions differently than prescription labels do.
   b. People do not understand the directions.
   c. People believe the doctor misdiagnosed them.
   d. People believe the pharmacist overcharged them.

3. Which of the following is a true statement?
   a. Approximately 20 percent of all prescription dollars spent in the U.S. are wasted through non-compliance.
   b. Generally, visuals used in counseling on directions distract the patient and confuse more than help.
   c. Reflective questions are usually resented by patients.
   d. Suggestive questions should be avoided unless no other questioning works.

4. The 1975 Millis Report stated that pharmacists of the future will be:
   a. largely replaced by computers.
   b. more concerned with dispensing accuracy.
   c. principally females.
   d. transmitters of information.

5. All of the following are true statements about pharmacist/patient communication EXCEPT:
   a. most patients want it.
   b. printed directions sheets may confuse the patient.
   c. the end result is better compliance.
   d. FDA advised consumers to establish a good rapport with physicians rather than pharmacists.

6. According to information presented in this article, what percentage of consumers indicated that if the pharmacist looked extremely busy, they would not bother him with questions?
   a. 20
   b. 50
   c. 70
   d. 90

7. Which of the following is the barrier to pharmacist-patient communication of greatest concern according to information presented in this article?
   a. Clerks
   b. Physicians
   c. Registers
   d. Rx counter

8. In a pharmacist-patient encounter, the strongest impression (message) is reportedly conveyed by the:
   a. pharmacist's body language.
   b. pharmacist's tone and facial expression.
   c. physical layout of the pharmacy.
   d. wording of the directions.

9. Which of the following questioning techniques is represented by "Are you following your doctor's directions?"
   a. Close ended
   b. Open ended
   c. Direct
   d. Suggestive

10. The prescription label instructions "Take one capsule every four hours as needed for pain" contains a major point for patient confusion. What is it?
   a. Can two capsules be taken for the first dose?
   b. Does "every four hours" mean around the clock?
   c. What does "as needed" mean?
   d. Is the type of pain important?

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Hyperlipidemia

A Multi-Disciplinary Approach

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A Memorial To a Special Friend

Milton Sappe grew up in Southwest Baltimore in an area called Pigtown. Growing up he played football for the Police Boys Club and won the City Championship. Milton was an excellent student, graduating from City College taking advanced courses, one of only twelve students in the class. He then went on to the University of Maryland as a pre-medical student. After three years he left pre-med to follow in his father's footsteps to become a pharmacist. Milton's studies were interrupted when he was called to active duty as a Marine in the Korean War.

After the war he returned to pharmacy school and was graduated. The next year he married Betty, who is also a pharmacist and they had three children.

In 1962 Milton took over ownership of Sappe's Pharmacy from his father. This year marked the stores 54th of successful operation. During the following years, Milton was active in many organizations where he held the following offices:

President, Baltimore Metropolitan Pharmaceutical Association
President, Maryland Pharmacists Association
President, Baltimore Cosmopolitan Club
Member, Mayor's Advisory Committee on Small Businesses
Member, President's Club, University of Maryland
Member, David Stewart Association, School of Pharmacy

Milton's favorite organization was ''The Affair of the Heart'' of which he was the National Chairman. Milton incorporated his greatest joy, ballroom dancing, into an organized dance where people could go to have an elegant and fun evening of dancing with all proceeds from the dances going to The American Heart Association.

Milton's contributions to pharmacy in Maryland will be sorely missed. He will always be remembered for his quiet kindness, diplomacy, and dedication.

Elwin Alpern, P.D.

President

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This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Advising Consumers on Antihistamines: A Clinical Update

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to review the recent FDA findings on OTC antihistamines, and present important points for counseling consumers on these drugs.

in the service of pharmacy

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Objectives

At the conclusion of this lesson, successful participants will be able to:

1. identify antihistamines that are safe and effective for self-administration;
2. demonstrate an understanding of antihistamines in general, and doxylamine in particular, regarding their potential for causing birth defects;
3. select the warnings required on labeling of OTC antihistamine-containing products; and
4. choose from a list, relevant points of advice to pass on to consumers who wish to self-medicate with antihistamines.

Recent developments in antihistamine therapy guidelines have spurred renewed interest in these widely used drugs. Previous articles in this series on OTC products have discussed the use of these agents in common colds and seasonal allergies, and as sleep aids and antinauseants.

More recently, FDA published its tentative final monograph (August, 1987) on OTC antihistamine drug products. This represents the final process before the agency issues its official monograph which will regulate the ingredients, indications, and labeling required for OTC sale of antihistamine-containing products.

This article will review the agency's actions, and stress recently published information.

Overview of Activity

Several major points were contained in FDA's announcement. These included adding chlorcyclizine and doxylamine to the list of safe and effective OTC antihistamine ingredients (Table 1), revising the "drowsiness" warning required on OTC product labeling, and addressing the question of whether or not doxylamine causes birth defects. This latter question is of special concern because of ongoing controversy and court cases involving the previously available doxylamine/pyridoxine combination prescription product, Bendectin.

Chlorcyclizine

This antihistamine has been commercially available under an approved NDA since 1949. In the 1950s, the Durham Humphrey Amendment to the Pure Food, Drug and Cosmetic Act exempted the 22 mg dosage form (i.e., Perazil) from prescription dispensing requirements.

Table 1

Antihistamines Approved for OTC Marketing*
Brompheniramine maleate
Chlorcyclizine hydrochloride
Chlorpheniramine maleate
Dexbrompheniramine maleate
Dexchlorpheniramine maleate
Diphenhydramine hydrochloride
Doxylamine succinate
Phenindamine tartrate
Pheniramine maleate
Pyrilamine maleate
Thonzylamine hydrochloride
Triprolidine hydrochloride

*Category I: Safe and effective for self-administration

During FDA's OTC review process from the early 1970s to the present, no data on chlorcyclizine were submitted to its cough and cold remedy advisory panel. So the antihistamine was not judged for appropriateness as an OTC product ingredient. This has raised questions both administratively and legally, as to what the drug's official status should be.

In its proposed rule, FDA stated that since adverse reaction reports first started to be required, there has been only one such report on chlorcyclizine. That report showed that it did not produce a therapeutic effect in patients. Due to evidence of its effectiveness, and a long history of marketing for safe self-administration, FDA concluded that chlorcyclizine should continue to be available without prescription.

The concern about the possibility of antihistamines causing birth defects encompasses the entire classification, including chlorcyclizine. Since the drug is a derivative of the OTC antiemetic cyclizine (Marezine), FDA required (in 1968) that its labeling include the warning: "Not for use by women who are pregnant or may possibly become pregnant, unless directed by a physician, since this drug may have the potentiality of injuring the unborn child." This warning was recommended to FDA by its Ad Hoc Advisory Committee on the Teratogenic Effects of Certain Drugs.

However, by 1975, another panel of experts concluded that there was insufficient evidence to prove there was a need for restriction in the use of cyclizine, chlorcyclizine, or meclizine (all piperazine derivatives), or for a pregnancy warning on the labeling.

Data on over 50,000 pregnant women, thousands of whom had taken these antihistamines during the early stages of pregnancy, showed that the occurrence of birth defects in their offspring was no greater, and possibly less, than their counterparts who did not take these agents.

In 1983, FDA re-examined its policies with respect to pregnancy warnings on OTC drugs and revised the requirements to state: "As with any drug, if you are pregnant or nursing a baby, seek medical advice of a health professional before using this product."

Since Perazil was removed from the market long ago, the commentary is of theoretical value only. The opposing argument is that FDA's mission is to determine safety and effectiveness of drugs, not to determine who markets what. Therefore, FDA believes that chlorcyclizine is safe and effective for OTC antihistamine use. This means that if a manufacturer wishes to market it as an OTC antihistamine, it can.

Drowsiness Warning Revised

Initially, antihistamine product labeling required a warning to the effect that concurrent ingestion of alcoholic beverages should be avoided. After reviewing information that other CNS depressants may also intensify the drowsiness effect of antihistamines, FDA proposed in its latest monograph that the labeling of OTC antihistamines be changed to read: "May cause drowsiness ("marked" drowsiness in the instance of diphenhydramine and doxylamine); alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers without first consulting your doctor. Use caution while driving a motor vehicle or operating machinery."

Because children may take prescription products containing sedatives or tranquilizers, products labeled for pediatric use must state: "May cause ('marked') drowsiness; sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers, without first consulting the child's doctor."

To review, Table 2 summarizes the information on sedatives and tranquilizers which was added to the warning required on OTC antihistamines.

Doxylamine

The most important conclusion elaborated by FDA in its latest notice concerned doxylamine. Long-used as a prescription and OTC antihistamine product ingredient, doxylamine had more recently plunged into disuse under the burgeoning shadow of litigation.

Table 2

Warnings Required on the Labeling of OTC Antihistamines

- May cause [marked*] drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.

- Use caution when driving a motor vehicle or operating machinery.

- As with any drug, if you are pregnant or nursing a baby, seek medical advice of a health professional before using this product.

- Do not take this product if you have asthma, glaucoma, emphysema, chronic pulmonary disease, shortness of breath, difficulty in breathing, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

*required for diphenhydramine and doxylamine

According to FDA ". . .controversy (has arisen) concerning whether or not there is an association with a prescription drug product containing doxylamine (Bendectin), and birth defects. This drug was widely prescribed as an antinauseant for use during pregnancy. Scientific and medical communities were actively discussing and debating whether doxylamine, in fact, played a direct or causal role in reported birth defects."

In response, FDA embarked on an extensive review of the scientific literature and comments submitted by interested parties. Some reviewers contended that studies alleging the occurrence of birth defects with doxylamine contained numerous flaws. These included the assessment of small numbers of subjects, lack of evaluation of other known causative factors for reported birth defects, the method of patient selection, and the methodology by which congenital defects were categorized.

The issue of limited study size contended that only 1,747 pregnant women were involved, and only six cases of a potential congenital problem, pyloric stenosis (see glossary), occurred in drug-exposed infants. Not only did the authors of the study warn against an ". . .interpretation of the causal relationship between maternal exposure and the occurrence of pyloric stenosis based upon their data," but also, a note in a prestigious medical journal later concluded that occurrence of pyloric stenosis in an infant actually correlated with appearance of nausea and vomiting in the pregnant woman, rather than exposure to any drug.

Representatives of the Royal College of General Practitioners in England and the German Research Society concurred. The latter organization concluded that there was *no* association between maternal exposure to doxylamine and the occurrence of pyloric stenosis.

Doxylamine has been alleged to cause several types of birth defects, including cleft palate/lip, heart defects, limb deformities, pyloric stenosis, spina bifida, and other anomalies. To assist the reader in making a more informed opinion on doxylamine's teratogenicity, a synopsis of the major studies to determine whether there is a causal relationship between its ingestion during pregnancy and the occurrence of birth defects is presented.

Pyloric Stenosis. One major study to assess whether doxylamine caused pyloric stenosis involved 4,337 newborns. On the surface, it could be interpreted that the drug was implicated because 6.3 percent of mothers of malformed babies reported using doxylamine during pregnancy, versus 4.6 percent of mothers of infants with the same defects, who did not take the drug. This appears to suggest there is a 40 percent greater chance for babies of mothers taking the drug to develop the anomaly.

However, when other variables were reviewed, such as smoking, time during pregnancy when doxylamine was taken, additional concurrent drug use, and exposure to other risk factors, the investigators concluded that it was unclear whether there is a direct causal relationship between the use of doxylamine and the occurrence of pyloric stenosis.

Another study involving 13,346 births over a five-year period was conducted to determine whether there was any such association. Of 3,835 women taking doxylamine during pregnancy, 13 delivered babies with pyloric stenosis. Interestingly, 13 other mothers who did not take doxylamine had babies with pyloric stenosis. The 13 in the latter group occurred in 9,511 pregnancies, or 40 percent more often than in the group who took the drug.

The investigators in this study reviewed factors such as maternal age and race, length of gestation, birth weight and sex of the infant, and calendar time of drug ingestion. Even though there may be evidence supporting the connection between taking doxylamine and the occurrence of pyloric stenosis, the investigators felt this interpretation is not warranted.

Another study involving more than 4,200 babies investigated the hypothesis that doxylamine increased the instance of pyloric stenosis in infants. This study demonstrated that 17 percent of infants whose mothers had taken doxylamine during pregnancy developed pyloric stenosis; 20 percent of those whose mothers did not take the drug, were born with the condition. The investigators concluded that exposure to doxylamine during pregnancy does not increase the risk of pyloric stenosis.

Cleft Palate/Lip. Two specific studies evaluating the possibility of a causal relationship between taking doxylamine during pregnancy and the occurrence of cleft palate/lip in newborns were cited by FDA in its August 1987 monograph. One involved 22 participating centers in the U.S. and Canada. The other was centered in England.

In the former study, investigators failed to find an appreciable increase in the risk of occurrence of cleft palate/lip (or occurrence of heart defects) for infants whose mothers took doxylamine during pregnancy. In the British study, investigators found a statistically significant greater number of babies born with cleft palate/lip of women who had taken doxylamine during pregnancy, than of those who did not take an antinauseant.

Nonetheless, the British investigators concluded that since there was a lack of consistent agreement in the literature, in spite of their findings in several other case reports, the author's study alone, did not prove that doxylamine caused birth defects. They went on to state that it is worth questioning whether prescribing the drug for pregnant women is advisable. In retrospect, this philosophy should be followed with all drugs unless they are absolutely necessary for the mother.

Glossary

ATRESIA: Birth defect resulting in the absence of or pathologic closure of a normal opening, passage or cavity.

CHOANAL ATRESIA: Failure of one or both sides of the nose to open up into the pharynx.

CLEFT PALATE/LIP: Also referred to as harelip. A birth defect where there is a slit in the upper lip or large opening (fissure) between the upper lip and one or both of the nostrils.

CONGENITAL CATARACT: An opacity of the crystalline lens of the eye, present at birth.

CRYPTORCHIDISM: Failure of the testes to descend into the scrotum.

ESOPHAGEAL ATRESIA: Failure of the full length of the esophagus to develop.

HYPOSPADIA: Defect in the wall of the urethra resulting in the opening being lower than the tip of the penis in males, or at a different than normal position in the vagina in females.

MEDULLOBLASTOMA: Brain tumor located in the area of the medulla.

PYLORIC STENOSIS: Narrowing of the pyloric sphincter, located between the stomach and duodenum.

RECTAL ATRESIA: Failure of the rectum to open and continue through the anal sphincter.

THYROGLOSSAL SINUS: Abnormality involving improper development of the thyroid and tongue.

Heart Defects. In a study of 1,644 pregnancies that was specifically looking at the effect of hormonal exposure before or during pregnancy, the investigators also assessed cardiovascular birth defects caused by other drugs including doxylamine. The studies found that 24 mothers whose babies were born with heart defects had taken doxylamine, versus 366 other babies with defects born of mothers who had not taken the drug. Forty-six of the mothers with normal babies reported that they had used doxylamine, and 1,200 others had not.

After analyzing the variables such as maternal age, contraceptive history, smoking, drinking alcoholic beverages, and taking other drugs prior to and during pregnancy, the investigators concluded that the possible association between doxylamine and heart defects was very weak.

Limb Deformities. Several groups have studied the relationship of use of doxylamine during pregnancy and limb deformities in newborns. One, accomplished in Australia over a five-year period, convinced investigators that the ingestion of doxylamine during pregnancy does not cause limb reduction deformities. Another study of pregnant women and their infants in the northwestern U.S. area, provided those investigators with evidence against a strong association between the use of doxylamine in pregnancy and occurrence of limb deformities in offspring of women taking it.

Does Doxylamine Cause Birth Defects?

The possibility that doxylamine, or any other drug, causes birth defects cannot be absolutely ruled out. In its August 1987 proposed rule, FDA cited over 200 studies of pregnant women and their offspring. The studies analyzed pregnancy that had produced infants with birth defects, including central nervous system disorders, choanal atresia, chromosome disorders, cleft palate/lip, congenital cataracts, congenital heart disease, congenital ureteral obstruction, cryptorchidism, esophageal atresia, hypospadias, insulin-secreting tumors, limb deformities, medulloblastoma, pyloric stenosis, rectal atresia, and thyroglossal. (See the Glossary for an explanation of these terms.)

Over and above the earlier mentioned investigations, FDA reviewed 16 additional studies. These involved in excess of 330,000 women and their infants.

The overwhelming evidence appears to support FDA's conclusion that it is unlikely that doxylamine is teratogenic.

There are some outside FDA who believe that, because there is a small chance that doxylamine causes birth defects, the drug should not be available OTC because women may take it during the critical first trimester of pregnancy for morning sickness and nausea.

This belief is countered with the fact that doxylamine has been available as an OTC antihistamine since the 1950s, and there is no evidence that pregnant women have ever taken it to self-medicate their nausea. The prescription form of doxylamine (combined with pyridoxine as Bendectin) was voluntarily removed from the market by its manufacturer due to escalating insurance costs, not because FDA required the manufacturer to do so due to a teratogenic potential.

The agency agreed with the latter opinion. OTC doxylamine must be labeled for use only as an antihistamine and contain the warning: "As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product." This, FDA believes, will prevent unauthorized use and allow a safe and effective antihistamine to be available to the general public.

Antihistamines Revisited

In summary, the August 1987 announcement added two antihistamines (chlorcyclizine and doxylamine) to the list of those approved for OTC sale in the U.S. It lessened the warning on taking OTC products while pregnant, and added a warning about concurrent use of tranquilizers and sedatives while taking antihistamines.

The official, approved indications for OTC antihistamines remain as before, for relief of symptoms of hayfever and upper respiratory allergies (allergic rhinitis) and the symptoms of sneezing, runny nose and watery eyes associated with the common cold. Antihistamines used as antiemetics are indicated for nausea and vomiting associated with motion sickness. Other OTC indications include temporary relief of cough, and as a sleep aid. The warning against the use of antihistamines in patients with asthma and other chronic obstructive pulmonary diseases, glaucoma, and enlarged prostate, without first consulting with their doctor, remain.

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Indication: Lower respiratory infections, including pneumonia, caused by *Streptococcus pneumoniae, Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β-hemolytic streptococci)
Contraindication: Known allergy to cephalosporins
Warnings: CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN SENSITIVE PATIENTS PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS

Administer cautiously to allergic patients

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis
Precautions:

- Discontinue Ceclor in the event of allergic reactions to it
- Prolonged use may result in overgrowth of nonsusceptible organisms
- Positive direct Coombs' tests have been reported during treatment with cephalosporins
- Ceclor should be administered with caution in the presence of markedly impaired renal function Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include

- Gastrointestinal (mostly diarrhea): 2.5%
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] and toxic epidermal necrolysis or the above skin manifestations accompanied by arthritis/arthralgia, and frequently, fever). 1 5%, usually subside within a few days after cessation of therapy Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor No serious sequelae have been reported Antihistamines and corticosteroids appear to enhance resolution of the syndrome
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely
- Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertonia, dizziness, and somnolence have been reported
- Other eosinophilia, 2%; genital pruritus or vaginitis, less than 1%, and, rarely, thrombocytopenia

Abnormalities in laboratory results of uncertain etiology

- Slight elevations in hepatic enzymes
- Transient fluctuations in leukocyte count (especially in infants and children)
- Abnormal urinalysis, elevations in BUN or serum creatinine
- Positive direct Coombs' test
- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinitest® tablets but not with Tes-Tape® (glucose enzymatic test strip, Lilly). [061088L]

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Dyslipidemia and Coronary Heart Disease

Coronary heart disease (CHD) is a major killer throughout the western world. In North America, for example, CHD is the leading cause of death in both men and women. In the United States, the American Heart Association estimates that almost five million individuals suffer from one or more forms of CHD and more than 500,000 die from heart attacks every year. It is estimated that in 1988 cardiovascular disease, which includes coronary heart disease, will cost Americans over $80 billion. (1)

About 85% of all deaths from cardiovascular disease result from atherosclerosis, a gradual build-up of fatty deposits (atherosclerotic plaque), which causes CHD when it occurs in the coronary arteries. (2) This build-up of atherosclerotic plaque, which can eventually clog the arteries and prevent blood from reaching the heart, often stems from abnormal levels of lipids and lipoproteins in the bloodstream.

Lipids are fats or fat-like substances. The major blood lipids are cholesterol and triglycerides. They cannot circulate in the blood alone; rather, they are transported in the form of complex molecules called lipoproteins. The major classes of lipoproteins include chylomicrons, very low density lipoproteins (VLDL), low density lipoproteins (LDL) and high density lipoproteins (HDL). (3)

Each of the lipoprotein families carries cholesterol and other lipids in different proportions. Chylomicrons originate in the intestine and are composed primarily of triglycerides (86%) derived from dietary fat. Chylomicrons transport dietary fat to adipose (fat) tissue and muscle for storage or utilization for energy. In the bloodstream, chylomicrons are very rapidly shorn of most of their triglycerides by an enzyme found in the capillary beds of adipose tissue and muscle. Chylomicron remnants are then removed rapidly from the bloodstream by the liver.

VLDL originates in the liver and is composed primarily of endogenous triglycerides (60%), which are made by the body, as opposed to those originating from dietary fat. In the bloodstream, VLDL undergoes much the same degradation as chylomicrons.

LDL (often referred to as the "bad" cholesterol) carries the majority of cholesterol in blood and delivers it, via specific cellular receptors, to a wide variety of cells where cholesterol is utilized to synthesize the following substances: bile acids, steroid hormones, and cellular membranes. If LDL does not bind to specific cell receptors, where it is drawn into the cell and degraded, it builds up in the bloodstream and contributes to the process of atherosclerosis.

HDL (the "good cholesterol"), on the other hand, helps to remove excess cholesterol from the tissues. Acting as a "scavenger," HDL is thought to pick up cholesterol from peripheral tissues, including the arterial wall, and return it to the liver where it can be degraded and excreted as bile acids.

LDL levels are strongly and directly related to risk for coronary heart disease. The higher the level of LDL, the greater the risk for CHD. (4,5,6) HDL, in contrast, appears to serve a protective role. The higher the level of HDL, the lower the risk for CHD. (7) This evidence suggests that increaesd CHD caused by imbalances of lipid levels in the bloodstream often cannot be measured in terms of one particular lipid or lipoprotein. Rather, the concentration of total cholesterol, triglycerides, HDL cholesterol, LDL cholesterol, and the ratio of total cholesterol to HDL and LDL to HDL should each be considered. (8)

While HDL and LDL cholesterol levels are powerful and independent predictors of CHD risk, they are not the only such predictors. Although the relationship between high triglyceride levels and CHD is controversial, high triglyceride levels have been associated with increased risk for cardiovascular disease. They have not been found, however, to be an independent predictor of risk for CHD, except in the Framingham Study, which found that plasma triglyceride levels predicted CHD risk for women. (9)

Dyslipidemias Associated with CHD

Several types of lipid transport disorders, or dyslipidemias, have been identified as increasing the risk for CHD. They can be defined simplistically as:

○ Hypercholesterolemia—This is defined as an abnormally high level of cholesterol in the blood. The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults considers ideal levels of total cholesterol to be below 200 mg/dL, LDL cholesterol to be below 130 mg/dL, and HDL cholesterol to be above 35 mg/dL. (10) Ideal ratios are total cholesterol to HDL cholesterol of less than 4 and LDL cholesterol to HDL cholesterol of less than 3.

○ Hypertriglyceridemia—Elevated levels of triglycerides constitute hypertriglyceridemia. Triglyceride levels vary with meals and normally range between 50 mg/dL and 250 mg/dL. In the fasting state they are usually lower than 200 mg/dL. Although there is no current evidence that hypertriglyceridemia *per se* independently elevates risk for CHD, many individuals with hypertriglyceridemia have very low levels of HDL that put them at increased risk. For example, in diabetic patients, whose metabolisms are compromised, triglyceride levels above 500 mg/dL with low levels of HDL are not uncommon and deserve intensive treatment. (11) Triglyceride levels above 1000 mg/dL require immediate treatment to prevent pancreatitis.

Consumption of excess fats, carbohydrates, alcohol or total calories can contribute to elevated triglyceride levels. Diets low in calories designed to achieve weight reduction can be effective in hypertriglyceridemia. When triglyceride levels are extremely high or diet is ineffective, drugs are available to control hypertriglyceridemia.

○ Mixed hyperlipoproteinemia—Patients who suffer from excess levels of cholesterol and triglyceride simultaneously have mixed hyperlipoproteinemia. Treatment of these patients may be more difficult than treatment of those with hypercholesterolemia or hypertriglyceridemia alone.

○ Hypoalphalipoproteinemia—This disorder is marked by *low* HDL cholesterol levels (below 35 mg/dL). High HDL retards atherosclerosis, and low levels increase the risk for CHD. HDL can be elevated nonpharmacologically by smoking cessation, increased exercise, and reduction in body weight. Some triglyceride lowering drugs can markedly elevate HDL levels.

Evidence for a Relationship between Dyslipidemia and CHD

A vast body of evidence links lipid and lipoprotein levels to CHD. Laboratory studies first showed that it was virtually impossible to produce atherosclerosis in animals without first increasing their blood levels of cholesterol. Genetic studies in man have shown that inheritance of high levels of LDL or low levels of HDL is associated with premature and severe CHD. Other studies have shown that an increase in dietary consumption of saturated fat and cholesterol is related to an increase in plasma cholesterol, which, in turn, has been directly related to atherosclerotic plaque formation and the clinical sequelae of atherosclerosis: angina, heart attack and sudden cardiac death. (12)

Prospective epidemiological studies have followed certain populations over time to determine how lipid and lipoprotein levels correlated with the occurence of CHD. One of the best known of these studies, the Framingham Study, begun in 1948 with 5,209 people and still continuing today, demonstrated a direct relationship between total and LDL cholesterol and CHD,

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and an inverse relationship between HDL cholesterol and CHD. (13)

Several large-scale clinical studies have examined the effect on CHD risk of lowering cholesterol by diet or diet and drug treatment. Although most of these studies were hindered by certain methodologic problems, they all showed, to some degree, that decreases in total and LDL blood cholesterol can result in a decrease in CHD.

Conclusive evidence of the benefit of lowering total and LDL cholesterol was obtained from the Lipid Research Clinics Coronary Primary Prevention Trial (LRC-CPPT). (14) In this double-blind study conducted by the National Heart, Lung and Blood Institute (NHLBI) and completed in 1983, 3,806 middle-aged men with high LDL cholesterol were placed on a low-fat, low-cholesterol diet and then given either a cholesterol-lowering drug (cholestyramine) or placebo. Over a seven-year period, an 8.5% difference in total cholesterol and a 12.6% difference in LDL cholesterol was observed between the two groups. Of even greater importance was the statistically significant 19% reduction in the incidence of CHD in the treated group compared with the group taking placebo.

The results of the LRC study indicated that for every 1% reduction in total cholesterol, the risk for CHD decreased by 2%. Subsequent reports from the study also noted that for every 1 mg/dL rise in HDL, the risk for CHD decreased by 4%.

Previous trials of low-fat diet alone or in combination with drug therapy had not achieved such clear-cut results. For example, while the Oslo Heart Study, in which participants were placed on a low-fat diet for five years, showed a significant reduction in cardiovascular events, it was not clear whether this was related entirely to cholesterol lowering or to a concomitant decrease in cigarette smoking. (15)

The Multiple Risk Factor Intervention Trial (MRFIT) showed only a minimal difference in cholesterol reduction between a specially treated group (in which high blood cholesterol, high blood pressure and smoking were modified) and a regularly treated group. (16) In addition, MRFIT showed no significant benefit of treatment for cardiovascular endpoints.

In the World Health Organization Clofibrate Trial, a 6% to 9% decrease in cholesterol occurred in patients treated with the drug clofibrate and was associated with a 20% reduction in the incidence of heart disease. (17) However, clofibrate also seemed to cause untoward side efects, some of which were fatal in a significant number of drug-treated patients.

More recent studies examining treatment of dyslipidemia have taken care to avoid some of the problems that plagued the earlier studies. The NHLBI Type II Coronary Intervention Trial studied the effects of lowering total and LDL cholesterol with the agent cholestyramine on the progression of coronary artery lesions, an indicator of CHD. (18) In this double-blind trial, 143 men and women with existing CHD and high levels of LDL cholesterol were placed on a low-fat, low-cholesterol diet and randomly assigned to receive either 24 g cholestyramine or placebo daily for 5 years. Of the 143 participants, 116 underwent coronary angiography, a diagnostic test that determines the extent of coronary artery lesions, both before and after two years of treatment to assess the progression of CHD.

After 5 years, results showed that there was a statistically significant difference between the two groups in the progression of CHD. Coronary angiography revealed that of the patients on placebo, 49% showed definite or probable progression of CHD compared with only 32% of those taking cholestyramine. The cholestyramine group also showed a 26% decrease in levels of LDL cholesterol and a 17% decrease in total cholesterol, while the group taking placebo showed only a 5% reduction in LDL cholesterol and a 1% reduction in total cholesterol.

Another study that measured the progression of CHD, the Cholesterol-Lowering Atherosclerosis Study, found that individuals on a treatment regimen of diet and the lipid-lowering agents colestipol and niacin showed significant decreases in total and LDL cholesterol and triglyceride, and a significant increase in HDL when compared with those on diet alone. (19) These changes were associated with a significant decrease in atherosclerotic plaque progression, as well as with an increase in plaque regression, in the drug treatment group.

The most recent drug intervention trial, the Helsinki Heart Study, produced conclusive results of the benefit of elevating HDL cholesterol. (20) The study found, for the first time, that increasing HDL and decreasing LDL with the drug gemfibrozil significantly reduced the rate of fatal and nonfatal heart attack and sudden cardiac death in patients with high blood cholesterol. Overall, there was a 34% reduction in CHD, which increased to 50% during years three to five of treatment, and to 67% in year five alone.

In this randomized, double-blind clinical trial, 4,081 middle-aged men with dyslipidemia were placed on a low-cholesterol diet and given either 600 mg gemfibrozil twice daily or placebo. Averaged over the five years of the trial, gemfibrozil lowered total cholesterol by 10%, LDL cholesterol by 11%, and triglyceride by 35%, and increased HDL by 11% compared with the placebo group. (21) In addition, the Helsinki Heart Study confirmed earlier reports that gemfibrozil is safe for the long-term treatment of lipid disorders.

These important studies have provided evidence to show that dyslipidemia is causally related to CHD and that CHD can be delayed, or even prevented, by risk-factor modification—including lowering total and LDL cholesterol and increasing HDL cholesterol by dietary or drug intervention or both.

Continued on Page 20.

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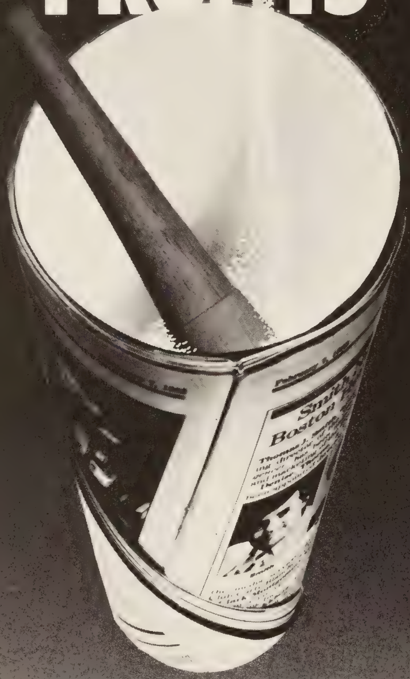

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New Guidelines for the Detection and Treatment of High Blood Cholesterol

Scott S. Kuperman, B.S. Pharm.
Ilene H. Zuckerman, Pharm.D.

This is a summary of the report issued by an expert panel of the National Cholesterol Education Program which describes the latest guidelines for the treatment of high blood cholesterol in adults. For those interested in the original report, it can be found in Arch Intern Med 1988;148:36–69.

Elevated blood cholesterol levels, especially low density lipoprotein (LDL)-cholesterol, have been proven to increase the risk of coronary heart disease (CHD). This risk rises progressively with increasingly higher cholesterol levels. There is substantial evidence that lowering total and LDL-cholesterol reduces the incidence of CHD, as does raising the levels of high density lipoprotein (HDL)-cholesterol. It is the opinion of this panel that all adults over the age of twenty should be periodically assessed to determine their risk of CHD. This is accomplished by measuring serum total and LDL-cholesterol; the panel has determined that a total cholesterol level of <200 mg/dL is "desirable", 200 to 239 mg/dL is "borderline-high", and ≥240 mg/dL is "high" blood cholesterol. At the time of these measurements, a determination of the presence of any other risk factors for CHD should also be made. A listing of these risk factors can be found in Table 1. The appropriate next step depends on the values of these two factors. A schematic of the decision-making process involved in determining what, if any, therapy is required can be found in Figures 1–4.

Either LDL-cholesterol or total cholesterol values may be used to monitor therapy. Although LDL-cholesterol measurements are preferred since LDL-cholesterol is more closely associated with CHD, total cholesterol values are usually easier and less expensive to obtain. Treatment goals for lowering LDL-cholesterol and total cholesterol are:

	CHD absent and <2 CHD risk factors	CHD present or ≥2 CHD risk factors
LDL-cholesterol	<160 mg/dL	<130 mg/dL
Total cholesterol	<240 mg/dL	<200 mg/dL

Diet Therapy: If intervention is deemed necessary, based on the panel criteria, the first line treatment should always consist of dietary modifications. Dietary therapy is a two-step process which is designed to progressively lower intake of cholesterol and saturated fats (See Table 2). The Step-One Diet involves lowering total fat to less than 30% of calories, saturated fatty acids to less than 10% of calories, and cholesterol to less than 300 mg/d. This can be achieved without radical modification of diet; the patient merely avoids some of the more obvious sources of fats (See Tables 3 & 4). At the start of the diet, the patient's serum total cholesterol levels are measured and adherence to the diet is assessed at four to six weeks and at three months. If serum level goals are met, the patient enters

TABLE 1
Risk Status Based on Presence of CHD Risk Factors Other Than LDL-Cholesterol

The patient is considered to have a high risk status if he or she has one of the following:
- Definite CHD: the characteristic clinical picture and objective laboratory findings of either:
  - Definite prior myocardial infarction, or
  - Definite myocardial ischemia, such as angina pectoris
- Two other CHD risk factors:
  - Male sex*
  - Family history of premature CHD (definite myocardial infarction or sudden death before 55 years of age in a parent or sibling)
  - Cigarette smoking (currently smokes more than ten cigarettes per day)
  - Hypertension
  - Low HDL-cholesterol concentration (below 35 mg/dL confirmed by repeated measurement)
  - Diabetes mellitus
  - History of definite cerebrovascular or occlusive peripheral vascular disease
  - Severe obesity (≥30% overweight)

* Male sex is considered a risk factor in this scheme because the rates of CHD are three to four times higher in men than in women in the middle decades of life and roughly two times higher in the elderly. Hence, a man with one other CHD risk factor is considered to have a high-risk status, whereas a woman is not so considered unless she has two other CHD risk factors.

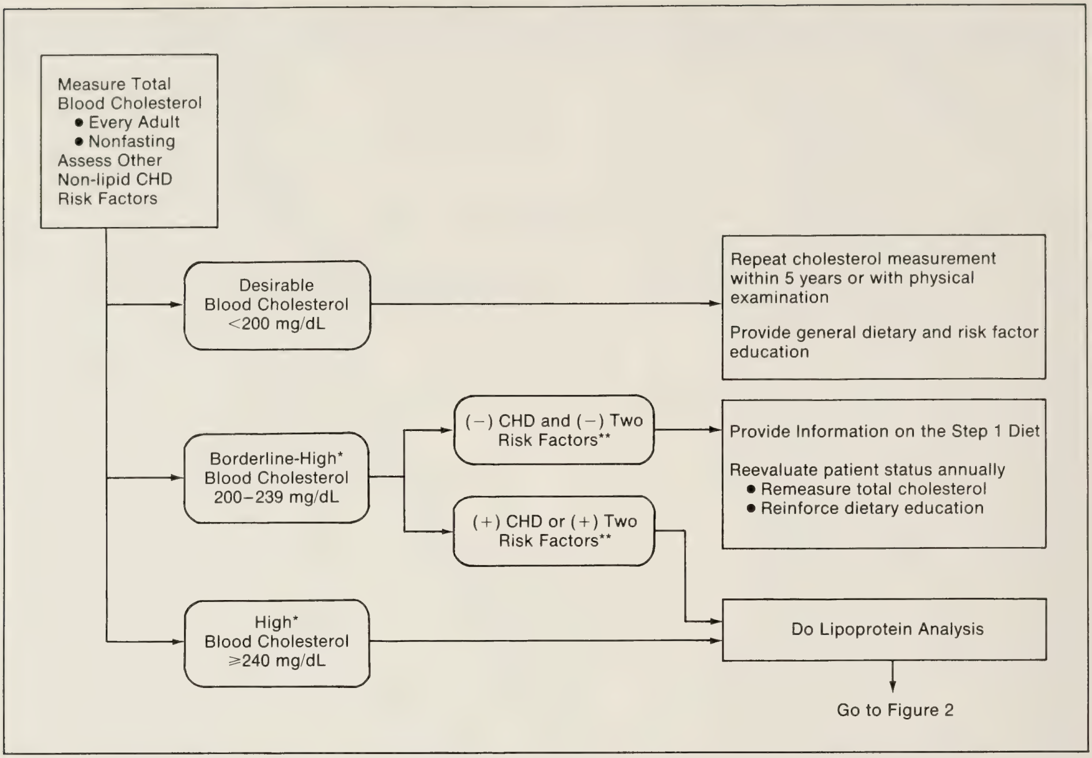
Measure Total Blood Cholesterol
• Every Adult
• Nonfasting
Assess Other Non-lipid CHD Risk Factors
Desirable Blood Cholesterol <200 mg/dL
Repeat cholesterol measurement within 5 years or with physical examination
Provide general dietary and risk factor education
Borderline-High* Blood Cholesterol 200–239 mg/dL
(−) CHD and (−) Two Risk Factors**
Provide Information on the Step 1 Diet
Reevaluate patient status annually
• Remeasure total cholesterol
• Reinforce dietary education
(+) CHD or (+) Two Risk Factors**
High* Blood Cholesterol ≥240 mg/dL
Do Lipoprotein Analysis
Go to Figure 2

FIGURE 1. Initial classification based on total cholesterol. CHD indicates coronary heart disease; asterisk, must be confirmed by obtaining repeated measurements and then using the average value; double asterisks, one of which can be male sex.

a long-term monitoring program and should be seen by the physician quarterly for the first year and twice yearly thereafter to confirm therapeutic success.

If this diet is insufficient to lower serum total cholesterol to within the desired ranges after a course of at least six months, the Step-Two Diet should be initiated. This further reduces fats and cholesterol as follows: saturated fatty acids is less than 7% of calories and cholesterol to less than 200 mg/d. Monitoring should proceed as for the Step-One Diet: re-evaluation at four to six weeks and again at three months. If desired serum levels are attained, the patient then enters the long-term program.

Drug Therapy: If, after six months of diet therapy, the patient remains uncontrolled, drug therapy should be initiated. This should be in addition to, and not instead of, diet therapy.

Drug therapy should be considered in patients who, despite dietary intervention, have an LDL-cholesterol level ≥190 mg/dL with no risk factors, or a level ≥160 mg/dL associated with definite CHD or two risk factors. The agents of first choice include the bile acid sequestrants (cholestyramine, colestipol) and nicotinic acid. These agents are very effective at reducing the risk of CHD, but require considerable patient education. Cholestyramine (Questran®) and colestipol (Co-

TABLE 2
Dietary Therapy of High Blood Cholesterol Level

	Recommended Intake	
Nutrient	Step-One Diet	Step-Two Diet
Total fat	Less than 30% of total calories	Less than 30% of total calories
Saturated fatty acids	Less than 10% of total calories	Less than 7% of total calories
Polyunsaturated fatty acids	Up to 10% of total calories	Up to 10% of total calories
Monounsaturated fatty acids	10% to 15% of total calories	10% to 15% of total calories
Carbohydrates	50% to 60% of total calories	50% to 60% of total calories
Protein	10% to 20% of total calories	10% to 20% of total calories
Cholesterol	Less than 300 mg/d	Less than 200 mg/d
Total calories	To achieve and maintain desirable weight	To achieve and maintain desirable weight

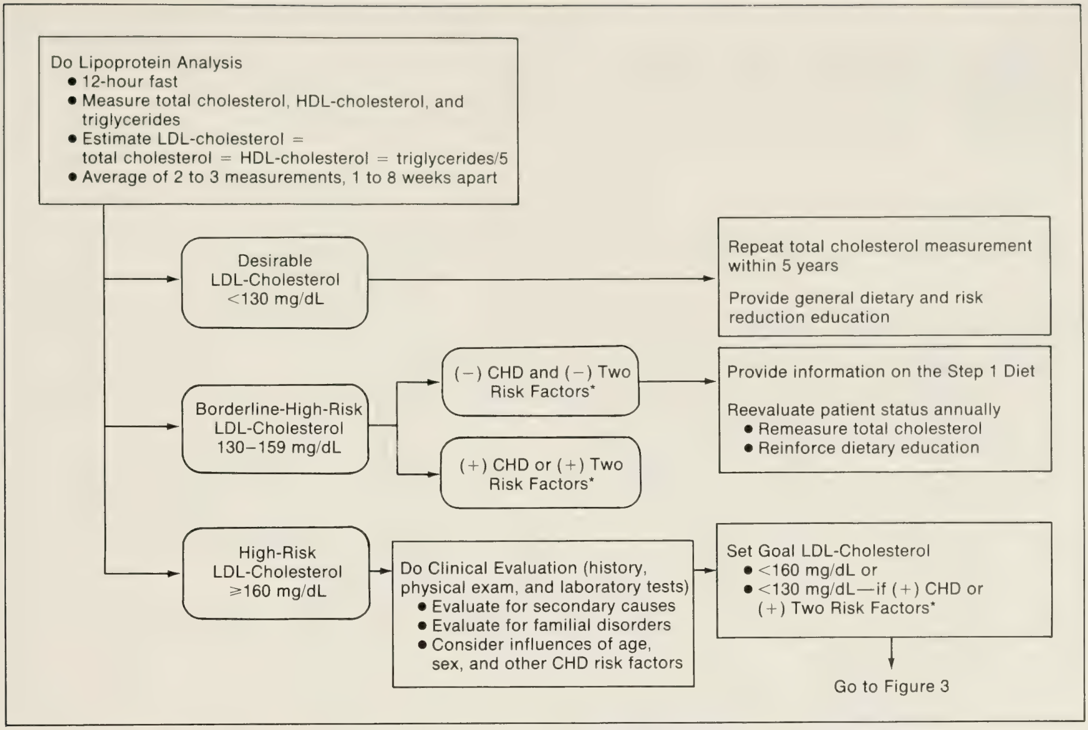
Do Lipoprotein Analysis
• 12-hour fast
• Measure total cholesterol, HDL-cholesterol, and triglycerides
• Estimate LDL-cholesterol = total cholesterol = HDL-cholesterol = triglycerides/5
• Average of 2 to 3 measurements, 1 to 8 weeks apart
Desirable LDL-Cholesterol <130 mg/dL
Repeat total cholesterol measurement within 5 years
Provide general dietary and risk reduction education
Borderline-High-Risk LDL-Cholesterol 130–159 mg/dL
(−) CHD and (−) Two Risk Factors*
(+) CHD or (+) Two Risk Factors*
Provide information on the Step 1 Diet
Reevaluate patient status annually
• Remeasure total cholesterol
• Reinforce dietary education
High-Risk LDL-Cholesterol ≥160 mg/dL
Do Clinical Evaluation (history, physical exam, and laboratory tests)
• Evaluate for secondary causes
• Evaluate for familial disorders
• Consider influences of age, sex, and other CHD risk factors
Set Goal LDL-Cholesterol
• <160 mg/dL or
• <130 mg/dL—if (+) CHD or (+) Two Risk Factors*
Go to Figure 3

FIGURE 2. Classification based on low density lipoprotein (LDL)-cholesterol. Asterisk indicates one of which can be male sex; CHD, coronary heart disease; HDL, high density lipoprotein.

lestid®) work by binding bile acids, thus causing the liver to synthesize more bile acids from cholesterol. Since the drugs are not absorbed, there are no systemic toxicities, only local GI effects. Constipation, bloating, belching, flatulence, and nausea are all possibilities. The drugs can, however, interfere with the absorption of other medications; so, the patient should be advised to take other meds either one hour before or four hours after the bile acid sequestrants. These agents must be mixed well with fluid (water, fruit juice, soup, or milk). The choice of one or the other depends on individual patient preference, since both work in a similar fashion.

Nicotinic acid (Niacin, Nicobid®) is the preferred agent in those patients with concurrent hypertriglyceridemia (triglyceride levels ≥250 mg/dL), since the sequestrants tend to increase triglyceride levels. It lowers total and LDL-cholesterol and triglyceride levels while raising HDL-cholesterol levels. Although it is currently the least expensive antihyperlipidemia agent, patient acceptance is limited due to its unpleasant side effects. Flushing, skin warmth, and headache are all common problems; but they can be diminished by pretreatment with aspirin or nonsteroidal anti-inflammatory drugs, slowly increasing the dose, avoiding administration on an empty stomach, or employing the more expensive sustained-release form. In any case, tolerance to these side effects usually develops in a few weeks with continued use. However, the flushing will return if the patient omits doses (a definite incentive for compliance!).

The next choice would be the so-called "HMG CoA reductase inhibitors"; lovastatin (Mevacor®) is the only one currently on the market. These agents block the formation of cholesterol early in its biosynthesis. This results in lowered levels of LDL- and VLDL-cholesterol and triglycerides and slightly increased levels of HDL-cholesterol. So far, side effects seem to be generally minor (changes in bowel function, headaches, nausea, fatigue, insomnia, and myalgias); but liver function changes and the formation of lens opacities have been noted. Thus, it is important for the patient to have baseline and routine follow-up measurements of liver function and ophthamological exams. For maximum effectiveness, lovastatin should be taken with meals. Lovastatin's long-term safety has not been proven yet, since it is so new on the market (See Table 5).

Other available drugs include gemfibrozil and probucol. Gemfibrozil (Lopid®) is actually approved only for lowering triglyceride levels to prevent pancreatitis; but it is occasionaly used as a single agent antihyperlipidemic in those patients who can't tolerate the resins or nicotinic acid. More often, it is employed concurrently with one of the first choice agents. It is of particular interest as it seems to significantly increase HDL-cholesterol levels. Recent data suggest that gemfibrozil

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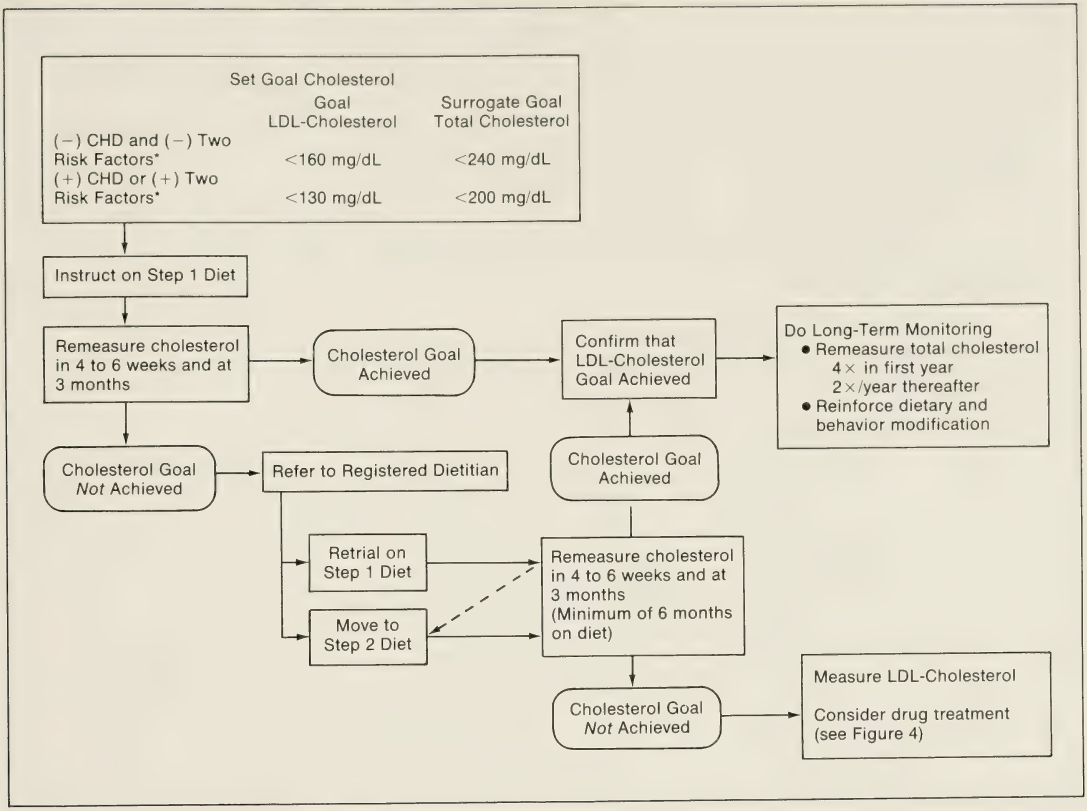

Set Goal Cholesterol
Goal LDL-Cholesterol
Surrogate Goal Total Cholesterol
(−) CHD and (−) Two Risk Factors*
<160 mg/dL
<240 mg/dL
(+) CHD or (+) Two Risk Factors*
<130 mg/dL
<200 mg/dL
Instruct on Step 1 Diet
Remeasure cholesterol in 4 to 6 weeks and at 3 months
Cholesterol Goal Achieved
Confirm that LDL-Cholesterol Goal Achieved
Do Long-Term Monitoring
• Remeasure total cholesterol 4× in first year 2×/year thereafter
• Reinforce dietary and behavior modification
Cholesterol Goal Not Achieved
Refer to Registered Dietitian
Cholesterol Goal Achieved
Retrial on Step 1 Diet
Move to Step 2 Diet
Remeasure cholesterol in 4 to 6 weeks and at 3 months (Minimum of 6 months on diet)
Cholesterol Goal Not Achieved
Measure LDL-Cholesterol
Consider drug treatment (see Figure 4)

FIGURE 3. Dietary treatment. Asterisk indicates one of which can be male sex; LDL, low density lipoprotein; CHD, coronary heart disease.

TABLE 4
Cholesterol and Fat Content of Animal Products in Three-Ounce Portions (Cooked)

Source	Cholesterol Content, mg/3 oz	Total Fat Content, g/3 oz	Source	Cholesterol Content, mg/3 oz	Total Fat Content, g/3 oz
Red meats (lean)			Fish		
Beef	77	8.7	Salmon	74	9.3
Lamb	78	8.8	Tuna, light canned in water	55	0.7
Pork	79	11.1	Shellfish		
Veal	128	4.7	Abalone	90	0.8
Organ meats			Clams	57	1.7
Liver	270	4.0	Crab meat		
Pancreas (sweetbreads)	400	2.8	Alaskan King	45	1.3
Kidney	329	2.9	Blue crab	85	1.5
Brains	1746	10.7	Lobster	61	0.5
Heart	164	4.8	Oysters	93	4.2
Poultry			Scallops	35	0.8
Chicken (without skin)			Shrimp	166	0.9
Light	72	3.8			
Dark	79	8.2			
Turkey (without skin)					
Light	59	1.3			
Dark	72	6.1			

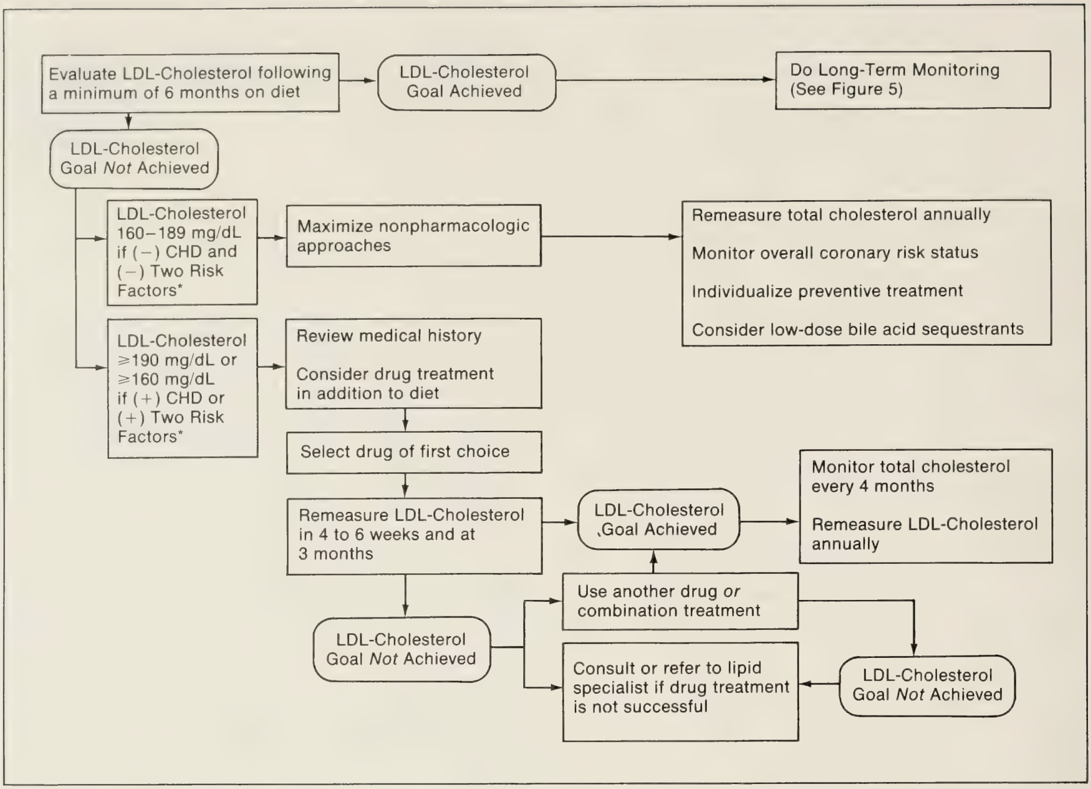

Evaluate LDL-Cholesterol following a minimum of 6 months on diet
LDL-Cholesterol Goal Achieved
Do Long-Term Monitoring (See Figure 5)
LDL-Cholesterol Goal *Not* Achieved
LDL-Cholesterol 160–189 mg/dL if (−) CHD and (−) Two Risk Factors*
Maximize nonpharmacologic approaches
Remeasure total cholesterol annually
Monitor overall coronary risk status
Individualize preventive treatment
Consider low-dose bile acid sequestrants
LDL-Cholesterol ≥190 mg/dL or ≥160 mg/dL if (+) CHD or (+) Two Risk Factors*
Review medical history
Consider drug treatment in addition to diet
Select drug of first choice
Monitor total cholesterol every 4 months
Remeasure LDL-Cholesterol annually
Remeasure LDL-Cholesterol in 4 to 6 weeks and at 3 months
LDL-Cholesterol Goal Achieved
Use another drug *or* combination treatment
LDL-Cholesterol Goal *Not* Achieved
Consult or refer to lipid specialist if drug treatment is not successful
LDL-Cholesterol Goal *Not* Achieved

FIGURE 4. Drug treatment. Asterisk indicates one of which can be male sex; LDL, low density lipoprotein; CHD, coronary heart disease.

may be an alternative to nicotinic acid as a second line agent in certain patients However, further study is necessary to define more clearly gemfibrozil's role in the treatment of hyperlipidemia. Gemfibrozil is well tolerated in most patients; usual side effects include GI upset, diarrhea, and muscle aches. Clofibrate (Atromid-S®) is a related compound; but its use has fallen into disfavor due to evidence of serious long-term toxicity.

Probucol (Lorelco®) reduces both LDL- and HDL-cholesterol, thus its role in therapy is uncertain. It is sometimes used as a single agent in those patients who cannot tolerate other medications or as combination therapy. It is generally well tolerated; side effects include diarrhea, flatulence, abdominal pain, and nausea. However, it does prolong the QT interval, so it is contraindicated in patients with ventricular irritability. It should be taken with meals for maximum effect (See Table 6).

After starting drug therapy, the LDL-cholesterol level should be measured at four to six weeks and again at three months. If the response to therapy is adequate, the patient should be seen every four months to monitor cholesterol therapy and side effects. Long-term monitoring of serum total cholesterol levels is acceptable with lipoprotein analysis once a year.

If single agent therapy is unsuccessful, the patient should be switched to another or to a combination of more than one drug. The combination of a bile acid sequestrant with either nicotinic acid or lovastatin may lower LDL-cholesterol by 45% to 60%.

Drug therapy is likely to continue for many years or for a lifetime. Thus, diet therapy alone should be unequivocably ruled out as a possibility. Also, the patient must be impressed with the importance of adherence to both diet and drug therapy in order to avoid the consequences of uncontrolled hyperlipidemia. Individualized therapy is a must. It is up to all health care providers to devise the most convenient, as well as the most effective, therapy to ensure patient compliance. Furthermore, they should periodically monitor the patient's progress and encourage continued adherence to dietary and medication regimens.

TABLE 3
Recommended Diet Modifications to Lower Blood Cholesterol

	The Step-One-Diet	
	Choose	Decrease
Fish, chicken, turkey, and lean meats	Fish, poultry without skin, lean cuts of beef, lamb, pork or veal, shellfish	Fatty cuts of beef, lamb, pork; spare ribs, organ meats, regular cold cuts, sausage, hot dogs, bacon, sardines, roe
Skim and low-fat milk, cheese, yogurt, and dairy substitutes	Skim or 1% fat milk (liquid, powdered, evaporated), buttermilk	Whole milk (4% fat): regular, evaporated, condensed; cream, half and half, 2% milk, imitation milk products, most nondairy creamers, whipped toppings
	Nonfat (0% fat) or low-fat yogurt	Whole-milk yogurt
	Low-fat cottage cheese (1% or 2% fat)	Whole-milk cottage cheese (4% fat)
	Low-fat cheeses, farmer or pot cheeses (all of these should be labeled no more than 2 to 6 g of fat per ounce)	All natural cheeses (eg, blue, roquefort, camembert, cheddar, Swiss), low-fat or "light" cream cheese, low-fat or "light" sour cream, cream cheeses, sour cream
	Sherbet, sorbet	Ice cream
Eggs	Egg whites (2 whites equal 1 whole egg in recipes), cholesterol-free egg substitutes	Egg yolks
Fruits and vegetables	Fresh, frozen, canned, or dried fruits and vegetables	Vegetables prepared in butter, cream, or other sauces
Breads and cereals	Homemade baked goods using unsaturated oils sparingly, angel food cake, low-fat crackers, low-fat cookies	Commercial baked goods: pies, cakes, doughnuts, croissants, pastries, muffins, biscuits, high-fat crackers, high-fat cookies
	Rice, pasta	Egg noodles
	Whole-grain breads and cereals (oatmeal, whole wheat, rye, bran, multigrain, etc)	Breads in which eggs are a major ingredient
Fats and oils	Baking cocoa	Chocolate
	Unsaturated vegetable oils: corn, olive, rapeseed (canola oil), salflower, sesame, soybean, sunflower	Butter, coconut oil, palm oil, palm kernel oil, lard, bacon fat
	Margarine or shortenings made from one of the unsaturated oils listed above, diet margarine	
	Mayonnaise, salad dressings made with unsaturated oils listed above, low-fat dressings	Dressings made with egg yolk
	Seeds and nuts	Coconut

TABLE 5
Drugs Highly Effective in Lowering LDL-Cholesterol*

Drug	Starting Dose	Maximum Dose	Usual Time and Frequency	Side Effects	Monitoring
Cholestyramine, colestipol	4 g twice daily, 5 g twice daily	24 g/d, 30 g/d	Twice daily, within an hour of major meals	Dose-dependent upper and lower gastrointestinal tract	Dosing schedules of coadministered drugs
Nicotinic acid	100–250 mg as single dose	3 g/d, rarely, doses up to 6 g are used	Three times a day with meals to minimize flushing	Flushing, upper gastrointestinal tract and hepatic	Uric acid, liver function, glucose
Lovastatin	20 mg once daily with evening meals	80 mg/d	Once (evening) or twice daily with meals	Gastrointestinal tract and hepatic, miscellaneous, including muscle pain	Liver function, creatine kinase, lens

* LDL indicates low density lipoprotein.

TABLE 6
Summary of the Major Drugs for Consideration*

Drugs	Reduce CHD Risk	Long-term Safety	Maintaining Adherence	LDL-Cholesterol Lowering, %	Special Precautions
Cholestyramine, colestipol	Yes	Yes	Requires considerable education	15–30	Can alter absorption of other drugs, can increase triglyceride levels and should not be used in patients with hypertriglyceridemia
Nicotinic acid	Yes	Yes	Requires considerable education	15–30	Test for hyperuricemia, hyperglycemia, and liver function abnormalities
Lovastatin†	Not proven	Not established	Relatively easy	25–45	Monitor for liver function abnormalities, and possible lens opacities
Gemfibrozil‡	Not proven	Preliminary evidence	Relatively easy	5–15	May increase LDL-cholesterol in hypertriglyceridemic patients; should not be used in patients with gallbladder disease
Probucol	Not proven	Not established	Relatively easy	10–15	Lowers HDL-cholesterol; significance of this has not been established; prolongs QT interval

* CHD indicates coronary heart disease; LDL, low density lipoprotein; and HDL, high density lipoprotein.
† Recently approved by the Food and Drug Administration for marketing.
‡ Not approved by the Food and Drug Administration for routine use in lowering cholesterol. The results of the Helsinki Heart Study should be available soon to define the effect on CHD risk and long-term safety.

Continued from page 14.

Diagnosing and Managing Dyslipidemia

Over the years, treatment guidelines for high blood cholesterol have been issued in the United States. The most recent guidelines, released in November 1987 by the NCEP Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, have defined more strictly than ever before cholesterol levels considered desirable. (10) The panel has designated new classifications of cholesterol levels and has updated treatment protocols for all Americans over age 20. The ranges are as follows:

Classification Based on Total Cholesterol

<200 mg/dL	Desirable Blood Cholesterol
200–239 g/dL	Borderline-High Blood Cholesterol
>240 mg/dL	High Blood Cholesterol

Classification Based on LDL Cholesterol

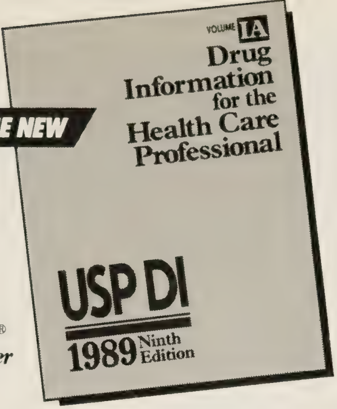
<130 mg/dL	Desirable LDL Cholesterol
130–159 mg/dL	Borderline-High Risk LDL Cholesterol
>160 mg/dL	High-Risk LDL Cholesterol

The NCEP committee recommends that individuals with a cholesterol level of 200 mg/dL or greater and two other risk factors, such as male sex, hypertension, cigarette smoking, diabetes, obesity, a family or personal history of CHD, or HDL <35 mg/dL, have specific lipoprotein levels measured. Anyone with a total cholesterol level over 240 mg/dL, regardless of other risk factors, should also be evaluated further. Unlike previous guidelines, which recommended that only total cholesterol be evaluated, the new recommendations require quantification of LDL cholesterol before a treatment decision can be reached.

LDL cholesterol concentrations below 130 mg/dL are considered desirable. Recommendations regarding diet may be given to individuals whose LDL levels are between 130 mg/dL and 159 mg/dL and who do not have other risk factors. Individuals with LDL levels between 150 mg/dL and 189 mg/dL should be vigorously treated with dietary therapy, and individuals with LDL values above 190 mg/dL should also be vigorously treated with dietary therapy and, if diet fails, drug therapy. Lipid-lowering drugs are recommended for individuals with LDL levels above 160 mg/dL who also have other CHD risk factors.

Treating Dyslipidemia

As in earlier guidelines, dietary therapy is recommended by the NCEP as the primary cholesterol-lowering treatment. The Step 1 diet, low in fat (<30% of calories), saturated fats (<10% of calories), and cholesterol (<300 mg/day) is advised. If this proves insufficient, the Step 2 diet, which further reduces saturated fats and cholesterol intake, is prescribed. If patients fail to respond adequately to diet, and LDL cholesterol levels are not lowered to below the recommended cutpoints after six months, the panel recommends the use of certain lipid-lowering agents in combination with dietary therapy. The NCEP guidelines list cholestyramine, colestipol and nicotinic acid as drugs of first



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choice and gemfibrozil, probucol and lovastatin as major drugs for consideration.

Many of the agents currently available and recommended as lipid-modifying agents have drawbacks, however, which limit their tolerability and reduce patient adherence—the extent to which patients follow the advice of health professionals in maintaining a treatment regimen. Adherence is commonly referred to as "compliance." Although some agents have been found to be efficacious, safe and generally well tolerated, others have been associated with serious side effects and some have not yet been proven effective in reducing risk for CHD.

Nicotinic acid is effective in lowering cholesterol and has been proven safe for long-term use, but it also has serious side effects that affect its tolerability and limit its acceptance by patients. These side effects include flushing, excess uric acid in the blood, abnormalities in liver function, and gastro-intestinal side effects. Nicotinic acid may not be tolerated in postmenopausal women with flushing or in patients with angina or extensive coronary disease.

Gemfibrozil, a fibric acid derivative, has been found to be efficacious and safe. Although it is well tolerated in most patients and is associated with few side effects, some patients experience gastrointestinal symptoms and occasional changes in liver function tests.

Lovastatin, an HMG-CoA reductase inhibitor, is effective in reducing LDL cholesterol, but its long-term safety and its effects on CHD endpoints have not been established. Lovastatin is associated with headaches, nausea, fatigue, insomnia, skin rashes, muscle pain and inflammation. Clinical trials with lovastatin have also found a high prevalence of liver function abnormalities and lens opacities.

Probucol, another lipid-lowering agent, is less effective in lowering LDL cholesterol than the bile acid sequestrants, nicotinic acid or lovastatin. Furthermore, it has been shown to reduce by as much as 25% levels of HDL cholesterol, a protective factor for CHD. The long-term safety of probucol and its effect on CHD risk have not been proven. Probucol is generally well tolerated, although such side effects as diarrhea, flatulence, abdominal pain, and nausea occur in some patients. It has also been found to interfere with the normal pumping of the heart by prolonging the Q-T interval.

The safety and efficacy of the bile acid sequestrants, cholestyramine resin powder and colestipol, have been proven in clinical studies, but their benefits are offset by poor patient adherence. Both agents are considered by patients to be inconvenient because they must be measured and mixed with liquids before ingestion, and unpalatable because of their gritty texture and aftertaste. ●

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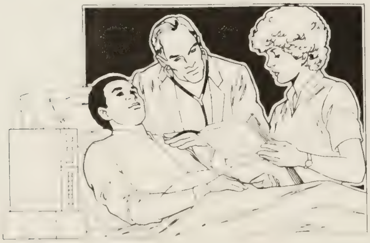

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GLOSSARY

ANGINA PECTORIS: Chest pain caused by lack of oxygen and blood to the heart. Commonly called angina.

ANGIOGRAPHY: X-ray of blood vessels after introduction of contrast material; used as a diagnostic aid in determining atherosclerosis and myocardial infarction.

APOLIPOPROTEIN: The protein component of lipoproteins; it helps maintain lipoprotein structure and regulate function and metabolism; each of 5 groups (A, B, C, D & E) contains subgroups (i.e., A-I, A-II).

ATHEROSCLEROSIS: A slowly progressive disease involving the accumulation of plaque on the inner walls of the arteries. Plaque consists of cholesterol and other lipids, fibrous tissue and cellular debris; eventually its accumulation can result in closure of the arteries. If the coronary arteries are affected, angina, heart attack or sudden death may result.

CHD: *C*oronary *H*eart *D*isease. A disease state involving compromise of the coronary artery system which supplies blood to the heart. Abnormal levels of blood cholesterol are a major risk factor for CHD.

CHOLESTEROL: A lipid present in animal products, such as fats and egg yolk, and in the blood. A precursor of bile acids and steroid hormones, cholesterol facilitates the transport of fatty acids and circulates in the blood as part of a lipid-protein complex called a lipoprotein. Increased levels of blood cholesterol are implicated in atherosclerosis and CHD.

CHOLESTYRAMINE (also called cholestyramine resin): A lipid-lowering drug belonging to the class of drugs known as bile acid sequestrants. Cholestyramine lowers blood cholesterol by enhancing the rate of removal of LDL cholesterol from the bloodstream.

CHYLOMICRONS: The largest of the lipoproteins, chylomicrons consist mainly of triglyceride, with small amounts of cholesterol, phospholipids and protein. Synthesized in the gastrointestinal tract, chylomicrons transport dietary fat to fat tissues and muscle for storage or utilization of energy.

DOUBLE-BLIND STUDY: A scientific study in which neither the subjects (patients) nor the investigators (treating physicians) know who is receiving the experimental drug and who is receiving a placebo (a control, or "sugar pill").

DYSLIPIDEMIA: A group of conditions characterized by abnormalities of serum lipids (including cholesterol) and lipoproteins. Dyslipidemia is an identified risk factor for CHD. It can be controlled by diet or diet and drug therapy.

ENDOGENOUS: Originating within the body.

EPIDEMIOLOGICAL: Pertaining to the study of the occurrence, distribution, and causes of health and disease in humans.

FREDRICKSON CLASSIFICATION SYSTEM: A method of classifying dyslipidemias according to specific abnormal lipoprotein concentrations (i.e. Type IIA, Type IIB, Type IV; most common types).

HDL: *H*igh *D*ensity *L*ipoprotein. A lipoprotein consisting of lipids and the apolipoproteins A-I, A-II, and C that is thought to be protective against coronary heart disease because it removes cholesterol from plasma and tissues and carries it back to the liver for excretion. Low plasma levels of HDL are associated with an increased risk for coronary heart disease.

HYPERCHOLESTEROLEMIA: A condition marked by an abnormally high level of cholesterol in the blood, generally above 220 mg/dL. Hypercholesterolemia, known as Fredrickson Type IIA, is marked by increased LDL cholesterol and normal levels of triglyceride and is the most common form of dyslipidemia. Cholestyramine in conjunction with diet is considered a first line of therapy for the treatment of hypercholesterolemia by the National Cholesterol Education Program (NCEP).

HYPERTRIGLYCERIDEMIA: A condition marked by an abnormally high level of triglyceride in the blood, generally above 250 mg/dL. It is a form of dyslipidemia.

HYPOALPHALIPOPROTEINEMIA: A condition marked by an abnormally low blood level of HDL cholesterol. Because HDL is involved in removing excess cholesterol from the tissues, hypoalphalipoproteinemia is a risk factor for coronary heart disease.

ISCHEMIA: A transient decrease in blood flow, and therefore in oxygen, due to an obstruction of a blood vessel.

ISCHEMIC HEART DISEASE: A diminished blood supply to the heart, commonly caused by obstruction of the coronary arteries.

LDL: *L*ow *D*ensity *L*ipoprotein. A lipoprotein subfraction consisting of lipids and apolipoprotein B that transports the major amount of cholesterol in the blood and delivers it to specific cellular receptors. LDL is 50% cholesterol by weight and normally accounts for 60% to 80% of the total cholesterol in the blood. High plasma levels are causally related to CHD. Cholestyramine lowers blood cholesterol by reducing the amount of LDL cholesterol in the body.

LDL RECEPTORS: Surface components of cell membranes that have a special affinity for LDL cholesterol.

LIPIDS: A class of fat-soluble organic substances, lipids are stored in the body as an energy reserve and serve a variety of important biological functions. Cholesterol, triglycerides and polylipids are types of lipids.

LIPOPROTEINS: A class of molecules comprising lipids and proteins. Synthesized primarily in the liver and intestine, lipoproteins are classified according to density and composition. Major classes include chylomicrons, HDL, LDL, and VLDL.

LRC-CPPT: *L*ipid *R*esearch *C*linics *C*oronary *P*rimary *P*revention *T*rial. A landmark study that directly demonstrated that lowering LDL cholesterol reduces risk for CHD. Results indicated that for every 1% reduction in total cholesterol (achieved with the cholesterol-lowering agent cholestyramine), risk for CHD decreases by 2%.

Mg/dL: Milligrams per deciliter. A measure of concentration of a substance. Lipids in the blood are measured in mg/dL.

MIXED DYSLIPIDEMIA: A type of dyslipidemia, called Fredrickson Type IIB, in which both cholesterol and triglyceride levels are elevated.

MYOCARDIAL INFARCTION: "Heart attack;" a process whereby a blood clot or atherosclerotic obstruction blocks the flow of blood to the heart, causing the death of cells in the heart muscle.

NATIONAL CHOLESTEROL EDUCATION PROGRAM (NCEP): A program launced by the National Heart, Lung and Blood Institute (NHLBI) in 1985, designed to reduce the prevalence of elevated blood cholesterol and contribute to a reduction in coronary heart disease morbidity and mortality by increasing the awareness and knowledge, among professionals and the public, of the importance of cholesterol as a risk factor for coronary heart disease.

NHLBI: The *N*ational *H*eart, *L*ung, and *B*lood *I*nstitute; a division of the National Institutes of Health involved in the research and development of effective means of prevention, diagnosis, and treatment of diseases of the heart and circulation.

PATIENT ADHERENCE: The extent to which an individual follows the advice of health professionals in maintaining a prescribed treatment regimen. Adherence, commonly referred to as "patient compliance," diminishes when treatment is inconvenient or dependent on an alteration in lifestyle.

PLACEBO: An inactive agent without therapeutic value used in controlled studies to determine the efficacy of a therapeutic agent against which it is being compared. The placebo is made to look exactly like the therapeutic agent.

PLASMA: The watery fluid portion of blood containing the white and red blood cells that transports nutrients as well as wastes throughout the body. Concentrations of lipids and lipoproteins are most often measured from blood collected as plasma.

SATURATED FAT: A type of fat found in animals and in oils that remains solid at room temperature. A diet high in saturated fats is frequently the cause of elevated total and LDL cholesterol levels.

SERUM: The fluid portion of whole blood that separates after coagulation. Concentrations of lipids and lipoproteins can be measured from blood collected as serum, although plasma is generally preferred.

SUDDEN CARDIAC DEATH: Sudden cessation of cardiac function and death, usually related to extensive coronary heart disease.

TOTAL CHOLESTEROL: Low density cholesterol (LDL) + very low density cholesterol (VLDL) + high density cholesterol (HDL). The National Cholesterol Education Program (NCEP) recommends that adults maintain a total cholesterol level below 200 mg/dL, as a higher level may increase risk for coronary heart disease.

TRIGLYCERIDE: A class of lipids that consist of fatty acids and glycerol. Triglyceride is the principal lipid in the bloodstream and is primarily transported by chylomicrons.

VLDL: *V*ery *L*ow *D*ensity *L*ipoprotein. A lipoprotein subfraction containing the apoproteins D, E, C, and lipids, mainly triglyceride. VLDL, synthesized in the liver, is degraded in the plasma to LDL.

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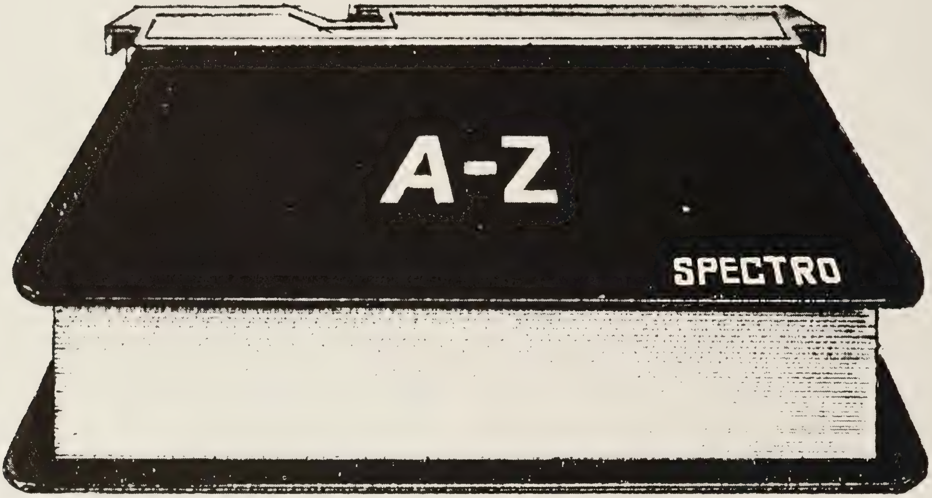

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Dickinson's Pharmacy

Jim Dickinson

An FDA role in mail Rxs? The October dismissal of the Iris Hemmelman manslaughter case against the country's largest mail-order drug company (*State of Idaho v. National Rx Services Inc. a/k/a Medco*) has raised a complex set of major issues in pharmacy.

As explained by Latah County Prosecutor Craig Mosman, the dismissal was based on the inability of the county (and perhaps by extension, also the state) to fund the bitterly contested case through years of courtroom wrangling and possible appeals.

Among assurances given the state by Medco was its promise to abide by the findings of a Nevada Board of Pharmacy "human factors" study of the stress-error ratios in the company's Las Vegas facility.

At the time of this writing, the results of that study were not public, but I am reliably informed that it showed departures from sound "human factors" principles.

"Human factors" engineering is a relatively new science that owes its origins to a syndrome first noticed during World War II, when the most-experienced bomber pilots began crashing on take-off more frequently than rookies. The only difference before and after the crashes started happening was a model change in the kind of aircraft flown, wherein the undercarriage-retract level above the pilot's head was relocated slightly.

The old pros were used to groping instinctively, with flawless accuracy, for the lever in the old model, but the young rookies had no such instincts, and always looked visually for the lever.

Because of the intense time pressure of war-time take-offs—the faster the undercarriage was retracted, the quicker the take-off, the sooner the mission was over, the more missions you could fly in a day—these few split-seconds were enough to cause crashes.

The discovery of this syndrome in the mind's complex relationship to time and the manipulation of close objects was the birth of "human factors" engineering.

Pharmacy, of course does not use "human factors" engineers. But, as mail-order pharmacy and some high-volume hospital and chain pharmacies are demonstrating, assembling-line time-and-function pressures may require it. Indeed, the National Association of Boards of Pharmacy is deep into a study of just this question.

In view of the Hemmelman death and other incidents, I decided not to wait for all this to transpire. In October, I filed a 100-page citizen's petition with the Food and Drug Administration, asking it to exercise its prerogative to regulate mail-order pharmacies under federal good-manufacturing practices regulations.

I did this under two premises—first, since mail-order facilities routinely break up prescriptions into different functions by different people and reassemble them at the end of the line, they are not pharmacies *per se*, but repackagers—and second, since state efforts to address this will be piecemeal and slow, avoidable injuries will occur unless a national standard is quickly imposed.

That national standard already exists in FDA good manufacturing practices regulations that require in-process quality assurance controls, known as "process validation."

In other words, the split-up and dispersed separate aspects of dispensing in mail-order pharmacies could not be peformed unless each step was separately validated by an in-house Quality Assurance unit, and the reassembly of the prescription at the end of the line similarly would have to be validated. And each act would have to be documented in a paper trail verifiable by FDA inspectors in biennial inspections. Obviously, this would slow down 20-prescriptions-plus-per-hour assembly lines all over the country.

I have discussed my petition with various regulatory pharmacists and do not find much enthusiasm for it.

First, there is skepticism that Iris Hemmelman's death is the tip of an iceberg at all, despite other mishaps that were not fatal. "Just an isolated, terrible tragedy," as Medco itself puts it.

Second, there is a feeling that to federalize the problem is to go against the tide of this entire decade—regulatory decentralization. Leave it to the states.

Third, there is disagreement that mail-order pharmacy is more "repackaging" than it is pharmacy to begin with. The future employment of pharmacists is felt to be trending to the high-volume facility, whether mail-order, hospital, or retail.

Mail-order is the wave of the future, and the profession of pharmacy had better get (and keep) a handle on it, some feel.

Anyone who has followed "Dickinson's Pharmacy" knows I do not buy that. I am for high-tech, high-touch personalized pharmacy for everyone, except where hardship requires inferior alternatives. High-volume, assembly-line dispensing is simply not my idea of a professional activity—it is technician work, like assembling an automobile in Detroit, you can get robots to do it.

The only judicial ruling that bears on this that I am aware of is *United States v. Sene X Eleemosynary Corp.* (479 Fed. Supp. 970 [S.D. Fla. 1979]), which was about a pharmacy that tried to escape FDA regulation of its topical procaine compounding operations, under the ruse of these being protected as "the practice of pharmacy."

In asserting that pharmacies are not exempt from FDA good manufacturing practices and other regulations, the court went to the trouble of saying what a genuine "pharmacy" is.

One characteristic of a true pharmacy is that the pharmacist has a one-on-one relaionship with the pharmacy's patients—"a customary characteristic in the usual practice of pharmacy." Another characteristic is that the prescriptions dispensed in a true pharmacy are "written by physicians who are known" to the pharmacist. And a third characteristic is that the bulk of a true pharmacy's prescriptions are not received from out of the state in which it is located.

The court's opinion is written loosely, but the point is surely made that *knowing* the prescriber and/or *knowing* the patient is legally important.

Conventional hospital and chain pharmacies of whatever prescription volume can probably satisfy one of those two criteria, if not both. No high-volume mail-order pharmacy can satisfy either, simply because of the logistical realities of interstate commerce.

And "interstate commerce" is the statutory threshold through which FDA regulation over *anything* is enabled. If you wish to add your comments to FDA's consideration of my petition, you may write to Dockets No. 88P-0367, Dockets Management Branch, FDA, 5600 Fishers Lane, Rockville, MD 20857.

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Institutional Forum

Patient Adherence To Treatment Regimens

Many physicians consider patient adherence—the extent to which patients follow the advice of health professionals in maintaining a prescribed treatment regimen—the most serious problem facing medical practice today. (1) Unfortunately, considerable nonadherence occurs whenever patients must administer their medications by themselves. It is estimated that, on average, only one third of patients correctly follow their physicians' directions. (2) About 50% of patients do not take prescribed medications according to instructions, and recommended changes in habitual behaviors are adhered to even less frequently. (3)

The medical community has, for years, taken steps to enhance adherence, which is commonly referred to as "patient compliance." These steps range from strategies to improve communication between physicians and patients, especially when giving medication instructions, to changes in drug forms by pharmaceutical manufacturers. To understand the importance of improving patient adherence, it is necessary to understand some of the reasons for nonadherence and the negative effects that occur as a result.

Nonadherence Has Widespread Effects

Patient nonadherence interferes with health care efforts in a number of ways. Most obviously, it disrupts or neutralizes the benefits of a given treatment. Failure to follow medical advice can also lead to such problems as additional and unnecessary diagnostic and treatment procedures, medication overdoses, and unnecessary medical expenses. Finally, nonadherence negatively influences patients' views about their health care. Some might say that much of the general dissatisfaction currently expressed toward health care delivery, as well as the negative reactions of physicians to "problem" patients, is the result of poor medical outcomes because of nonadherence. (2)

Poor adherence often surprises physicians, who may overestimate the degree of cooperation achieved among their patients. (2) They tend to blame nonadherence on the patient's personality and have little sympathy for or understanding of the uncooperative patient.

Physicians' own behavior, however, is sadly very much like that of their patients. (3) In a study of medical students who preregistered for a conference on patient adherence and were asked to adopt the role of patient by taking "medication" (vitamin C) for one week, prior predictions made about their adherence were confirmed almost exactly. (4) Only 21% of the students were totally adherent, despite the common perception that medical students would be especially adept at understanding and following instructions. In fact, their responses to an attitude questionnaire, such as "I saved the pills for when I am really ill," and "I didn't adhere because there was no therapeutic benefit," reflect the attitudes of many nonadherent patients asked to take medication for nonsymptomatic disorders, such as high blood cholesterol.

Issues Affecting Adherence

Attitudes such as those expressed by the medical students and by nonadherent patients in general, are common, and simply reflect the influence of experience. (2) Sometimes, despite poor adherence to a treatment regimen, patients recover or do not become ill. This may be due, however, to the wrong diagnosis, to a strong natural defense system, or to lessening symptoms of chronic illness.

On the other hand, faithfully adhering to a treatment regimen may not yield the desired outcome or may even make the patient feel worse. In this case, the diagnosis may have been incorrect, the patient may not have responded to a particular treatment, or the preventive measure may not have been sufficient. Furthermore, adverse effects of certain medications may make patients feel worse than they did before starting treatment, especially with such "symptomless" disorders as high blood cholesterol or high blood pressure.

Patients in these situations, therefore, feel that they need not take their physician's recommendations too seriously. Patient adherence, however, can be modified.

Methods of Enhancing Adherence

Adherence is based on a variety of factors, including how much information is given to patients by their physicians and how well they understand that information. In addition, adherence depends on how motivated patients are to adhere to their treatment regimen, how strongly patients believe that they can successfully change their behavior to produce the desired outcome, and how much support is offered by patients' family and friends. Adherence also depends on whether patients perceive their treatment as palatable. (2)

Physicians can foster adherence by making sure their patients understand the treatment instruction given them. In one study of patients with congestive heart failure, communication of instructions and information was inversely associated with errors in drug use —the better the communication, the lower the number of errors in use of medication. (5) In another study of clients of a neighborhood health center serving a low-income population, about 70% of patients who could correctly describe their physicians' instructions were actually adhering to their regimen. However, only 15% of patients who made one or more mistakes in describing their drug regimen were adhering to treatment. (6) Moreover, it has been shown that as many as one half of the physicians' statements are forgotten by the patient almost immediately. (7)

Adherence also is influenced by the degree to which patients feel able to control events and circumstances in their lives. (2) Feelings of powerlessness can result in failure to follow through with treatment regimens. Feelings of greater control over life in general, and over health matters in particular, are related to better adherence to dietary instructions and medication regimens. Similarly, the strength of a person's belief in his or her ability to undertake and maintain a behavior, such as smoking cessation, is an important determination of patient adherence.

The assistance and encouragement of family and friends can also help patients adhere to treatment regimens. Studies of weight control, for example, have shown that persons whose efforts to eat properly were reinforced by family members were more likely to maintain their weight loss. (8) In terms of adherence to treatment of an illness, success seems to be greatest when the family's normal roles and patterns are compatible with the patient's illness or when family members are willing to make accommodating changes in their lives and in the family environment. (9)

In general, adherence is reduced when a treatment regimen is complex, of long duration, dependent on an alteration of the patient's lifestyle, inconvenient, or expensive. (2) For example, in a study of patients with diabetes or congestive heart failure, medication errors occurred less than 15% of the time when only one drug was prescribed, increased to 25% when two or three drugs were prescribed, and exceeded 35% when five or more drugs were prescribed. (10) Another study found that when the complexity of a digoxin regimen was increased by adding it to a diuretic agent or a potassium supplement, aherence to the digoxin regimen notably decreased. (11)

Some pharmaceutical manufacturers have moved toward simplifying regimens by producing drug combinations and regimens requiring less-frequent dosing. These solutions sometimes create difficulties of their own. Combination and long-acting drugs can hamper the physician's flexibility in prescribing and dosing, and the patient may be paying for and taking unnecessary medications together with the essential ones. (12)

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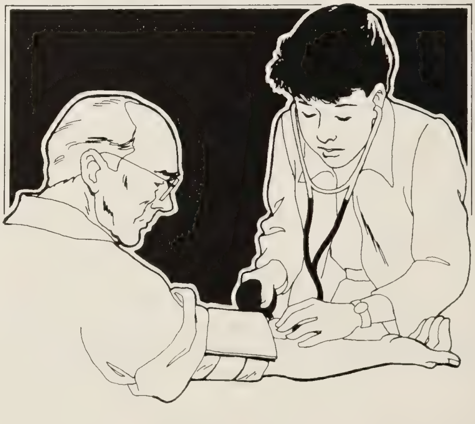

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Continuing Education Quiz

The Maryland Pharmacist MARCH, 1989

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by June 1, 1989. A continuing education certificate for one contact credit) will be mailed to you within 30 days. Please type or print clearly.

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Is this program used to meet your mandatory CE? [ ] Yes [ ] No

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How long did it take you to complete the program? ____________ minutes

Antihistamine Update

1. OTC antihistamines must contain a labeled warning about the potential for their aggravating which of the following diseases?
   a. Asthma
   b. Diabetes
   c. Heart disease
   d. Kidney disease

2. FDA has announced that:
   a. there is sufficient evidence that doxylamine causes birth defects to remove it from the OTC market.
   b. adequate labeling on OTCs containing doxylamine will prevent unauthorized use and allow its availability to the general public.

3. A birth defect that results in a failure of one or both sides of the nose to open up into the pharynx is a:
   a. choanal atresia.
   b. medulloblastoma.
   c. cleft palate.
   d. hypospadia.

4. In its 1987 notice, FDA stated that the term "marked" must be placed with the phrase "may cause drowsiness" (i.e., "may cause marked drowsiness") on the labeling of OTCs containing which of the following?
   a. Chlorpheniramine
   b. Doxylamine
   c. Triprolidine
   d. Dexbrompheniramine

5. In the same notice referred to in question #4 above, FDA announced that the drowsiness warning for OTCs was to be changed to include a statement that all of the following may increase the drowsiness effect of antihistamines EXCEPT:
   a. alcohol.
   b. pain killers.
   c. sedatives.
   d. tranquilizers.

6. OTC antihistamines must contain a labeled warning about their potential for aggravating which of the following?
   a. Glaucoma
   b. Hypertension
   c. Liver disease
   d. Thyroid disease

7. OTC antihistamines are indicated for treating all of the following conditions EXCEPT:
   a. allergic rhinitis.
   b. hay fever.
   c. morning sickness.
   d. runny nose.

8. Cryptorchidism is a term that refers to:
   a. a slit in the upper lip and one or both of the nostrils.
   b. improper development of the thyroid and tongue.
   c. narrowing of the oriface between the stomach and intestine.
   d. undescended testicles.

9. All of the following antihistamines are approved for OTC sale EXCEPT:
   a. dexchlorpheniramine.
   b. brompheniramine.
   c. diphenhydramine.
   d. tripelennamine.

10. The antihistamine that FDA ruled to be safe and effective for OTC use that has been removed from the market by its manufacturer is:
    a. meclizine.
    b. brompheniramine.
    c. dexchlorpheniramine.
    d. chlorcyclizine.

Classified

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

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calendar

March 1—Alumni Association Meeting
March 2—ASCO C.E. Program
March 12—BMPA Annual Banquet/Dance
March 18—UMAB/Rx Open House
March 19–24—National Poison Prevention Week
March 26—AZO Breakfast and CE
April 2—Hyperlipiedemia CE Seminar
April 8–12—APhA Annual Convention
April 16—AZO Breakfast Seminar and CE
May 4—Fritz Berman Seminar
June 4–8—ASHP Annual Convention
June 18–22—MPhA Annual Convention

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Commentary

YOUR 1989 CONVENTION! June 18–22, 1989

This year's convention will be our 107th. If you have never been to an MPhA Convention, or if it's been a long time since you've been to one, you're in for a real treat. This year's convention will be at the new Sheraton Ocean City Resort Hotel. The Delaware Pharmaceutical Society will be sharing their convention with us. There'll also be more than 150 family practitioners attending a University of Maryland seminar at the same time.

We are anticipating more than 50 exhibitors at our Trade Exposition. There will be more than 13 credit hours of continuing education credit for you to earn. We've scheduled plenty of time to see the exhibits, learn some new information in the continuing education seminars, meet for business sessions and still have lots of opportunity to hit the surf and sand.

Sunday, June 18, opens with hotel check-in and registration. We'll have a wine and cheese reception waiting for you at the registration desk. That evening, our annual Drug House Welcoming Cocktail Party will bring you together with your friends and acquaintances.

Monday, June 19, start off with continental breakfast, an excellent seminar focusing on long term care pharmacy changes, the opening of the Trade Exposition, afternoon CE and the Crab and Chicken Feast at the Berlin Fire Hall! Tuesday brings more ce, lunch in the exhibit hall, and a 1950's sock hop party at night! Wednesday morning will be our annual House of Delegates session and the Awards Banquet and Reception. Thursday will be the Simon Solomon Continuing Education Seminar in the morning.

In the past, attendees have commented on how "down to earth" and "relaxing" our conventions have been. So come on down to Ocean City and enjoy! I hope to see you at our biggest convention ever!

Elwin Alpern, P.D.

President

P.S. Turn to the middle of this issue for an extra registration form or call the office at (301) 727-0746.

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Correspondence Course

The Role of Aspirin in Prevention of Coronary Heart Disease

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to describe the action of low-dose aspirin on protecting against coronary heart disease.

in the service of pharmacy

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Gossel

Wuest

Objectives

At the conclusion of this lesson, the participant will be able to:

1. choose the correct mechanism of action, adverse reactions and precautions, as reported for low-dose aspirin therapy;
2. demonstrate an understanding of the theoretical importance for administering the correct dose of aspirin;
3. choose the most appropriate aspirin formulation or product to recommend for a particular situation; and
4. convey appropriate advice when counseling consumers on aspirin use.

There is evidence that aspirin protects against myocardial infarction (MI) and sudden death in certain cardiovascular diseases. This is a claim that *some* studies substantiate, and manufacturers of OTC aspirin products intimate to be true. Aspirin is indicated for this use when prescribed by a physician. However, American consumers are undoubtedly self-medicating based upon advertisements and articles they have read in the popular press.

This article examines the data which led to FDA approval of the indication of aspirin for decreased morbidity and mortality associated with certain cardiovascular diseases. It also summarizes more recent information which suggests that men who do not have a history of previous cardiovascular disease may also benefit from this therapy.

This article discusses the limitations of aspirin prophylaxis, stresses the importance of taking the proper dose, and cites the improvement in protection that some studies have shown can be expected. It also provides specific information to convey when counseling consumers on the use of aspirin for this indication.

Background

The results of numerous clinical trials have clearly demonstrated that aspirin decreases the chance for morbidity and premature death from certain cardiovascular diseases. It is approved for physician-supervised use to lower the risk of non-fatal myocardial infarction or death, in patients with unstable angina, or who had a previous MI. Such use is designated secondary protection, since these patients all have a previous history of cardiovascular disease.

Aspirin is also indicated in low doses to reduce the risk of recurrent transient ischemic attacks in men. Although these indications are included in the professional labeling, FDA does not permit these claims to be advertised for unsupervised self-medication with OTC products. Nonetheless, with publication of the results of a large study that showed that the chance of MI was decreased with prophylactic aspirin use, advertising and articles in the popular press and other media appeared directly to the public, claiming the virtues of this wonder drug for this purpose.

Cardiovascular Disease

Cardiovascular disease is a major health threat with approximately 1.5 million Americans experiencing a heart attack each year. This includes

Table 1

Representative OTC Aspirin Products

Product (Mfr)	Dosage Form	Strength
Alka-Seltzer (Miles Labs)	Tablet, effervescent	324 mg
Arthritis Pain Formula (Whitehall)	Tablet, buffered	486 mg
A.S.A. (Lilly)	Suppository	324 mg, 684 mg
A.S.A. Enseals (Lilly)	Tablet, enteric coated	325 mg, 650 mg
Ascriptin (Rorer)	Tablet, buffered	325 mg
Ascriptin A.D. (Rorer)	Tablet, buffered	325 mg
Ascriptin Extra Strength (Rorer)	Tablet, buffered	500 mg
Aspergum (Plough)	Gum tablets	227.5 mg
Asperbuf (Bowman)	Tablet, buffered	325 mg
Bayer (Glenbrook)	Tablet	325 mg
Bayer Children's (Glenbrook)	Tablet, chewable	81 mg
Buffaprin (Buffington)	Tablet, buffered	324 mg
Bufferin (Bristol-Myers)	Tablet, buffered	324 mg
Bufferin, Arthritis Strength (Bristol-Myers)	Tablet, buffered	486 mg
Bufferin, Extra Strength (Bristol-Myers)	Tablet, buffered	500 mg
Buffex (Mallard)	Tablet, buffered	325 mg
Buffinol (Otis Clapp)	Tablet, buffered	324 mg
Cama Arthritis Strength	Tablet, buffered	500 mg
Ecotrin (SmithKline)	Tablet, enteric coated	325 mg
Ecotrin Maximum Strength (SmithKline)	Tablet, enteric coated	500 mg
8-Hour Bayer (Glenbrook)	Tablet, (timed release)	650 mg
Empirin (Burroughs Wellcome)	Tablet	325 mg
Encaprin (Vicks Health Care)	Capsules, enteric coated granules	325 mg, 500 mg
Magnaprin (Rugby)	Tablet, buffered	325 mg
Magnaprin, Arthritis Strength (Rugby)	Tablet, buffered	325 mg
Maprin (Quantum)	Tablet, buffered	325 mg
Maprin I-B (Quantum)	Tablet, buffered	325 mg
Maximum Bayer Aspirin (Glenbrook)	Tablet	500 mg
Measurin (Winthrop-Breon)	Tablet, timed release	650 mg
Norwich Aspirin (Proctor & Gamble)	Tablet	325 mg
St. Joseph Children's Aspirin (Plough)	Tablet, chewable	81 mg
Wesprin Buffered (Wesley)	Tablet, buffered	325 mg

both MI and sudden death from cardiovascular complications. More than 350,000 of these victims die before reaching an emergency facility. Another 200,000 die within the first 24 hours. Of the survivors, about 10 percent die within the next year. Two-thirds of these victims die within the first six months, usually from recurrent infarction or sudden cardiac death. Those who survive beyond the first year experience a death rate of 3 to 5 percent per year.

However, this death rate has been slowly but steadily declining in the U.S. in recent years. This is probably due to better therapeutic intervention and to a general trend of Americans taking better care of themselves.

Thromboembolic occlusions in the coronary arteries are the major cause of morbidity and mortality in Americans. Blood clots inside of blood vessels are referred to as thrombi. When a thrombus breaks away and moves elsewhere, it is called an embolus. Emboli that lodge in and occlude coronary blood vessels result in MI and tissue death. Platelet plugs comprise most of the bulk of arterial thrombi. Platelet aggregation may also contribute to atherosclerosis development. An appropriate program to reduce morbidity and mortality, therefore, is to decrease the overall tendency of platelets to adhere to each other, or to blood vessel walls. This is the proposed mechanism of aspirin's prophylaxis potential.

Aspirin as Secondary Prophylaxis for Coronary Heart Disease

Antithrombotic agents suppress platelet activity. They are employed primarily to treat arterial thrombotic pathology. In contrast, **anticoagulant drugs** such as heparin and warfarin reduce the synthesis or activity of clotting factors. These actions are directed toward venous thrombotic disorders.

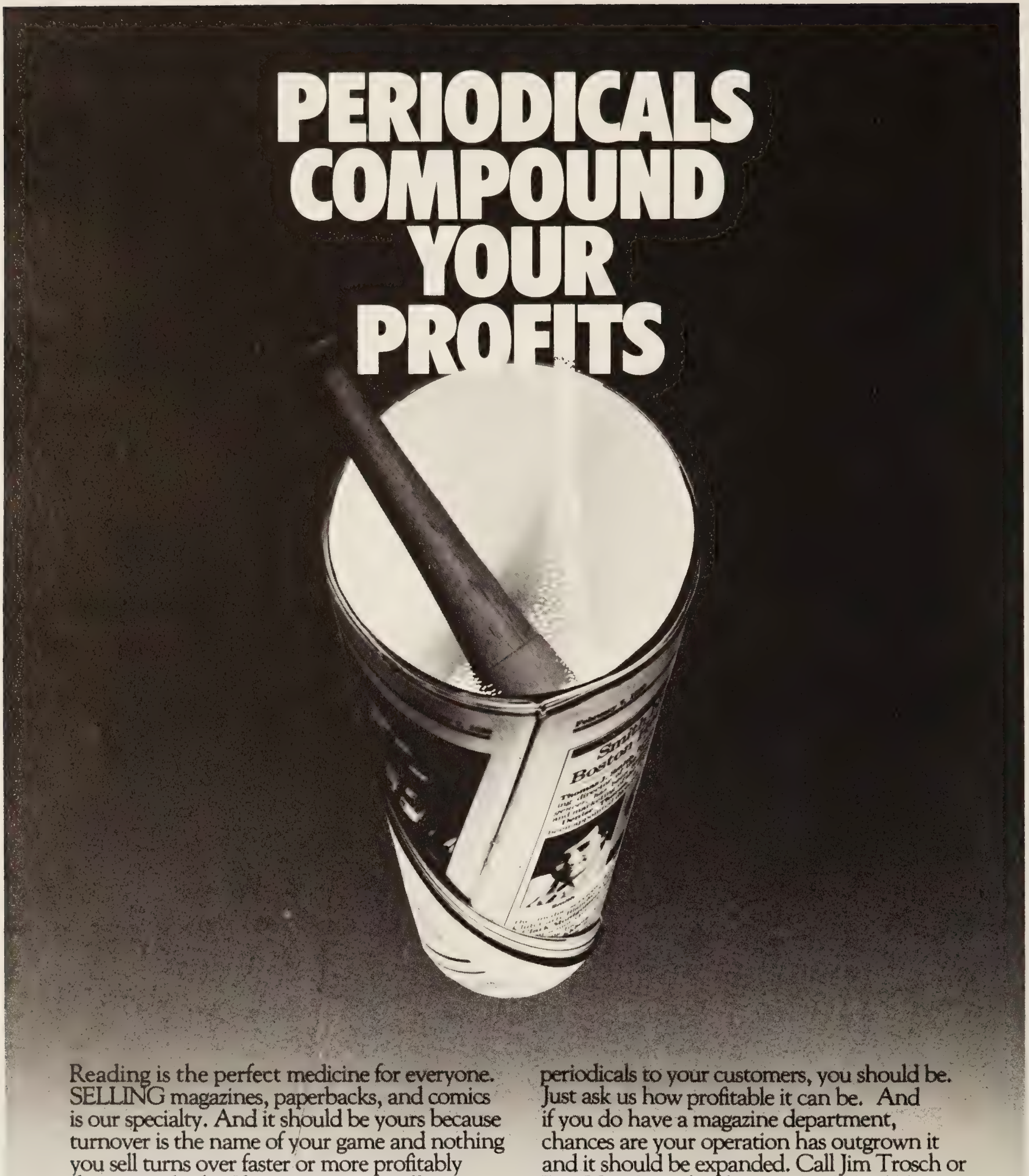
Aspirin has been suspected to have therapeutic value to individuals with coronary heart disease for more than 30 years. Two large clinical trials demonstrated its efficacy in patients with unstable angina. In one investigation, 31 of 625 (5 percent) of men who took a single 325 mg aspirin tablet each day for 12 weeks suffered an acute MI or died, versus an incidence of 65 of 641 (10 percent) of men who took a placebo. In the other study, men and women took either 325 mg aspirin four times/day for a mean duration of 18 months, or placebo. Seventeen of 176 (6.1 percent) of patients taking aspirin experienced an MI or died, compared to 36 of 179 (12.9 percent) of patients taking placebo. Both of these studies illustrated there was a 50 percent reduction in the risk for infarction and/or death in the aspirin-treated groups.

Another six studies were undertaken to assess aspirin's activity in post-MI patients. More than 10,800 predominantly male patients were involved. Aspirin was taken in doses ranging from 300 to 1500 mg/day, beginning three days to more than five years after the onset of their acute MI. Studies continued for intervals ranging from less than one to more than four years.

The pooled data revealed that there was an approximate 21 percent overall reduction for total or nonfatal reinfarction, and 16 percent overall risk reduction for cardiovascular death.

Aspirin as Primary Prophylaxis for Coronary Heart Disease

To evaluate whether aspirin con-



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veys primary protection, i.e., protects men who have never had an MI, 22,000 male U.S. physicians entered a clinical trial. Ages ranged from 40 to 84 years. Half of them received 325 mg buffered aspirin every other day, the others a placebo. After nearly five years of follow-up, the total number of myocardial infarctions among the physicians on aspirin was reduced 47 percent.

The incidence of hemorrhagic stroke was increased slightly, but the increase was not significant. Overall, aspirin did not affect the total number of vascular deaths or deaths from all causes. And when persons with nonfatal MI, nonfatal strokes, and vascular deaths from all causes were combined, the group receiving aspirin still had a 23 percent reduction in risk.

Another study involving approximately 500 British physicians showed that 500 mg aspirin/day did not significantly reduce the incidence of MI. The smaller size of the group and higher dose may account for the conflicting data.

Pharmacology of Antithrombotic Activity

Aspirin is believed to convey antithrombotic activity by inhibiting the enzyme cyclo-oxygenase in platelet membranes (Figure 1). This enzyme is responsible for converting arachidonic acid in the platelet membrane to the prostaglandin, thromboxane (TXA_2), a potent stimulant of platelet aggregation and vasoconstriction.

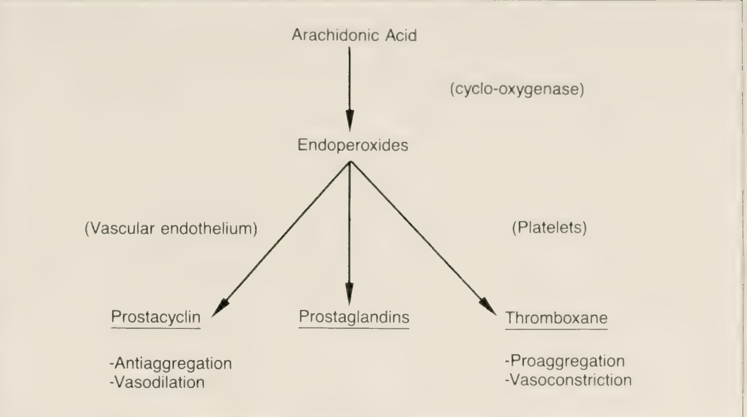

Figure 1. Biochemical pathway for prostacyclin, prostaglandins and thromboxane synthesis, showing site of aspirin-inhibition of cyclo-oxygenase.

A similar inhibitory reaction occurs in the endothelial cells of vascular tissue. There, cyclo-oxygenase is responsible for catalyzing formation of a different prostaglandin, prostacyclin (PGI_2). This is a potent inhibitor of platelet aggregation, and causes vasodilation. Of major importance is that inhibition of cyclo-oxygenase in platelets is irreversible; inhibition in vascular endothelium is reversible.

It is argued that aspirin could have a thrombogenic effect (i.e., stimulate thrombus formation) since aspirin blocks the production of PGI_2. This secondary reduction in PGI_2 levels could actually be detrimental to patients with thrombi, or to other high-risk patients who were predisposed to them. A thrombogenic effect from aspirin has indeed been demonstrated in animals. Extremely high doses (e.g., 200 mg/kg or more) are required to initiate thrombosis. In clinical studies of patients with rheumatoid arthritis or similar disorders who are treated with aspirin doses in excess of 3 gm/day, the drug has not shown such increased activity for thrombus formation. Individuals with congenital cyclo-oxygenase deficiency who are unable to synthesize both TXA_2 and PGI_2 also do not experience thrombotic episodes, and in fact, they actually have a mild tendency toward hemorrhage. From these and similar observations, it can be concluded that large doses of aspirin do not promote thrombogenic activity.

Its lack of thrombogenic action is partly related to characteristics of the platelets and endothelial cells. Platelets do not contain a nucleus and are unable to synthesize significant amounts of protein (enzyme). Once the enzyme is inhibited, antithrombotic activity is maintained for the life of the platelet, approximately 8.2 days. However, arterial vessel wall endothelial cells contain nuclei and synthesize new enzyme on demand. These cells completely recover from aspirin action in approximately 35 hours.

Other mechanisms may also contribute to aspirin's beneficial effects. For example, a mechanism that is unrelated to platelet cyclo-oxygenase inhibition has been demonstrated in uremic patients.

Most authorities agree that aspirin dosage must be regulated. This contrasts with evidence presented earlier that showed selective inhibition of TXA_2 synthesis, without appreciable effect on PGI_2 formation. The situation is compounded further because, within four hours following a low oral dose of aspirin, sufficient new platelets are formed and added to the circulation to initiate full platelet aggregation in response to precipitating factors. It only takes 10 percent of nonacetylated platelets of the total, to restore the blood's potential for full aggregation activity.

Antithrombotic doses of aspirin are reported to be 100 to 1000 mg/day, even though doses of 325 mg/day inhibit PGI_2 formation. Low doses of 40 to 60 mg/day selectively inhibit TXA_2, but not PGI_2 production. Limited studies have shown that 40 mg every 48 hours may have the maximum antithrombotic effect.

Because of its short half-life (2 to 3 hours), doses such as 20 mg every 4 to 6 hours (i.e., quartered pediatric aspirin tablets) may provide more effective drug action than a single 325 mg dose taken once a day. Investigation to confirm or deny the validity of these regimens has not been undertaken to date.

Aspirin Formulations and Derivatives

The only form of salicylate that

confers antithrombotic protection is aspirin. Nonacetylated derivatives of salicylic acid such as sodium salicylate, or magnesium- or choline salicylate, are not effective. Other nonsteroidal anti-inflammatory agents have not been evaluated.

Most studies have employed plain or buffered aspirin tablets. Similar cardioprotective property can be shown with enteric coated tablets, capsules and buffered aspirin in solution. However, one tablet of buffered aspirin in solution contains 24 mEq sodium which may not be suitable for persons with active sodium-retaining states such as renal failure or congestive heart disease.

Adverse Effects

Adverse effects of aspirin are dose-related, and restricted mainly to the gastrointestinal tract. Nausea, heartburn, stomach pain and constipation are common. A single dose of 325 mg of aspirin can cause measurable gastrointestinal bleeding.

Since all of these adverse effects relate to the presence of gastric acid, they can be minimized by neutralizing gastric contents with antacids, or reducing acid release with H_2-antagonists. Also, gastric distress can be minimized by taking enteric coated products. Buffered aspirin tablets contain insufficient alkalinizer to reduce acid secretion or protect against drug-induced mucosal erosion. They are no more effective in alleviating adverse gastric reactions associated with acid release, than nonbuffered aspirin tablets.

The risk of developing a gastric ulcer from taking aspirin has been shown to be dose-related; ulceration is unlikely if fewer than 15 tablets are taken per week. Moreover, persons with duodenal or gastric peptic ulcers heal while continuing to take prophylactic aspirin therapy. It is nevertheless prudent for persons with a history of peptic ulcer disease to restrict aspirin therapy or to use an enteric coated dosage form.

Individuals may occasionally experience respiratory and/or dermal symptoms characteristic of aspirin sensitivity. Such may occur within minutes, or several hours of a dose. The extent of allergy to aspirin is estimated to be less than 0.3 percent for the general population, and greater than 50 percent for patients with asthma, nasal polyps or severe atopy (a clinical hypersensitivity state that is influenced by heredity).

The extent of adverse reactions to 1000 mg aspirin/day was determined in a study of 4,500 people. The percentage incidence of unwanted response to aspirin and placebo, respectively, was: stomach pain (14.5 percent, 4.8 percent), heartburn (11.9 percent, 4.8 percent), and hospitalization for gastrointestinal disorders (4.9 percent, 3.5 percent). A slightly increased systolic pressure of 1.5 to 2.1 mm Hg, and diastolic pressure of 0.5 to 0.6 mm Hg was noted.

Counseling Consumers

Annual aspirin usage in the U.S. is reported to be as high as 20 thousand tons. Consumers may not place much confidence in its ability to reduce morbidity and mortality from heart disease since it is such a commonly used drug. But, because of potential benefit from low doses, its OTC availability and relative lack of side effects in antithrombotic doses, as well as its low cost, the use of aspirin prophylaxis to reduce the risk of myocardial infarction or recurrent transient ischemic attacks in men may make sense — as long as it is physician-supervised.

Most individuals involved in clinical trials have been males. It can be assumed that similar use in women is appropriate. The official product labeling does not discourage women from using aspirin; it notes only that there is a lack of available information to confirm efficacy.

A common question about aspirin use to reduce the incidence of coronary heart disease is, "Who will benefit?" The data are still not clear as to long-term ramifications. Any person who asks whether he might benefit from prophylactic aspirin dosing should be advised to discuss this with a physician. Therapy should proceed only under a physician's guidance. Pharmacists should inform consumers that self-therapy is not in their best interest.

Consumers should be told to take each dose with a glassful of water or milk, or a light snack. They should keep the bottle tightly closed between uses, and away from direct heat or moisture.

Patients should also remind their physician and dentist that they are taking aspirin before receiving any other treatment or taking any other drug. And they should discontinue therapy one week before undergoing surgery, unless their physician advises otherwise.

Persons who are at high risk of cardiovascular disease should follow their physician's recommendations to reduce the risk. Eighty to 90 percent of all cardiovascular disease in the U.S. is attributed to modifiable risk factors of hyperlipidemia, hypertension, obesity and smoking. Cigarette smoking is said to be the single most preventable cause of cardiovascular and noncardiovascular morbidity and mortality in the U.S. Altering these factors improves the prognosis that cardiovascular disease will be lessened.

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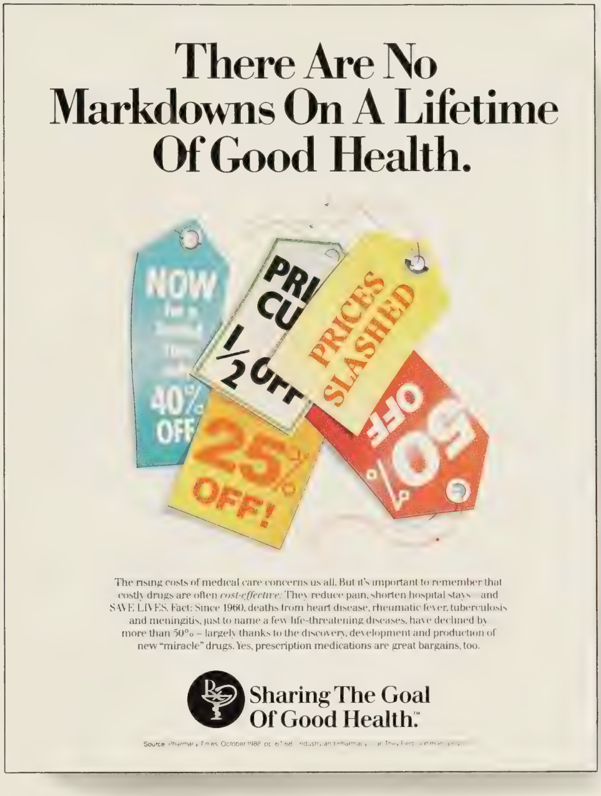

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Source: Pharmacy Times, October 1988 [illegible]

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Source: *Pharmacy Times,* October 1988, pp. 67-68. "Industry and Pharmacy: Can They Find Common Ground?"

Commentary

Dickinson's Pharmacy

by Jim Dickinson

Lowered expectations. If one of your professional satisfactions has come from the fact that public opinion polls repeatedly rank pharmacists at the top of the ladder of public esteem, consider this: It may be that the public is easy to please, pharmaceutically speaking.

West Virginia University pharmacy lawyer David B. Brushwood is among those who believe that, if true, this is a dangerous situation for the profession. A clientele that expects little may be satisfied by anything, including vending machines and mail-order suppliers.

If there is one pharmaceutical domain that can always be reserved exclusively for the live, flesh-and-blood pharmacist in one-on-one patient encounters it is that area where professional discretion is exercised—to dispense or not to dispense?

Brushwood has recently authored a videotape presentation for all pharmacy schools, "Ethics Perspectives," which dramatizes the ethical dilemmas that confront practicing pharmacists.

Consisting of 10 vignettes and 10 lengthier scenarios, the videotape addresses such topics as the monitoring of medical treatment, patient rights, disclosure of patient information, compliance with physician intentions, and current socioeconomic concerns.

One situation on the tape proposes that you have been filling prescriptions for an elderly couple for years, and know that the wife has Alzheimer's disease while the husband has been in stable health.

Recently, the health of both deteriorate. One day, the husband jokingly asks how much of his heart medication it would take to kill his wife. What should you say or do?

Brushwood's advice on the tape is to first contact the patient's physician.

"If the physician does not take action, the pharmacist is put into a unique situation," Brushwood told West Virginia University's magazine, *Pylons*. "In this case the husband is a competent decision maker and has the right to lead his life as he pleases. The wife, however, is not a competent decision maker because she is suffering from Alzheimer's. If the pharmacist suspects that the husband may endanger his wife's life, the pharmacist has a duty to intervene by informing the other family members."

Brushwood is among a growing number of thoughtful pharmacists who believe the profession has been given an easy, if not a privileged, ride in the societal changes that have been taking place for at least the past several decades.

As pharmacy technicians, dispensing physicians, mail-order firms and even 7-Elevens (via Rx-to-OTC switches) muscle into pharmacy's traditional "turf," the profession's comfort zone is being disturbed.

An understandable gut reaction has been to use political muscle in the opposite direction—to seek legislated bans on physician and mail dispensing, for instance.

Nice work, if you can do it. But increasingly in our pluralistic society, legislators are reluctant to interfere with anyone's way of making money—unless there is a convincing "body-count."

And even in the presence of a body-count, the tendency is to write rules as liberally as possible, so as to interfere as little as possible. The most recent case in point is the Prescription Drug Marketing Act of 1988 that pharmacy hoped would eliminate multi-tier pricing while eliminating the diversion market; instead, the law as passed narrowly limits only the most excessive (and least extensive) abuses—and it does so in a manner so feeble that cynics belive nothing will change in the long-run.

Discriminatory pricing, in other words, is still with us, and so is the broader diversion market, which is now sanitized under the euphemism, "secondary source market."

The law is still an achievement in protecting public health—but protecting pharmacy is not one of the things it does.

So if you can't get the law to protect you, who can you turn to? The answer has been known since Shakespeare: "The fault, dear Brutus, lies not in our stars but in ourselves if we are underlings."

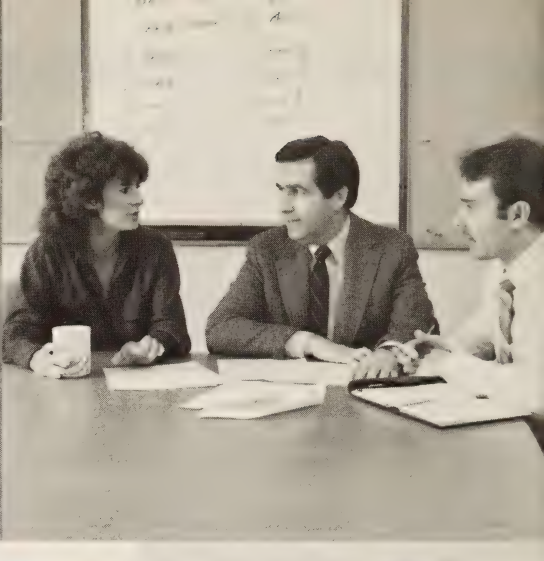
In other words, do not let the low expectations of the public in the past and third-party payors now, deter us from accepting Professor Brushwood's challenge.

It is in the risky area of decision-making, and the exercise of professional discretion, displayed most conspicuously in the counseling function, that pharmacy will succeed or fail in the future.

Do you dispense that partial refill for the traveler late on a Friday night? Do you invite a physician's patient to question his or her prescription? Do you divulge a patient's disease condition to that caller on the phone?

What are the trade-offs? By the quality of their judgments will pharmacists preserve the status of their profession—not by repackaging dosage units on the low expectations of purchasers.

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.



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A. *The Skin Defined . . . Our Complex Complexion*

* The skin is the largest organ of the body, and next to the human brain, the most complicated and least understood.

* Our bodies are made mostly of water, as much as 75% and somewhat less later in life.

* The skin covers the body's outer surface, an area of approximately **25 square feet** and weighing about **6 lbs.** The skin accounts for about **12%** of the weight of the body.

* The skin envelops the body completely and is also a continuation of the mucous membranes of the body's orifices; e.g., the mouth, nose, urethra, etc.

B. *The Skin's Vital Functions*

The skin provides a *barrier* against invasion by infectious agents. It offers the delicate tissues beneath it a large measure of *protection* against injury from the outside. The skin *regulates* body temperature by the expansion and contraction of its supply of capillaries and by the activities of sweat glands.

The skin participates in the excretion of the body's wastes, and through the production of melanin, the skin can ward off *some* of the damage of the sun's UV rays. It also helps transform sunshine into essential vitamin D.

The skin also provides an important route for the transmission of information to physicians. Mirroring our body's internal functions, skin's moistness, texture, smell and temperature help doctors form initial diagnoses. It is on the skin that diseases often make their most disturbing expression. The appearance of skin, including hair, scalp and nails, provides both social signals and clues to one's general state of wellness.

C. *The Language of the Skin*

Dermatology, the "language of the skin", developed slowly through the Middle Ages, when the catalogue of skin ailments continued to grow. Between 1750 and 1825, dermatology grew rapidly as a practical science. Antoine Charles Lorry, the founder of French dermatology, was the first to consider skin a living organ like other systems of the body. Lorry showed that skin diseases often developed from a variety of physiological and environmental causes. The vocabulary available to dermatologists expanded, bringing new approaches to the diagnosis of skin ailments, and establishing London and Paris as the dermatology capitals of Europe. With the 17th and 18th centuries came increased, detailed knowledge of anatomy and physiology with renowned European scientists and physicians unfolding discoveries and explanations of the skin and the gradual classification of the skin's "compartments" or structure.

D. *The Structure of the Skin*

Facial skin is a 3-layer basic structure: the epidermis, dermis and subcutis (subcutaneous/hypodermis) tissue. The tissue-paper-thin top layer of the epidermis is called the ***stratum corneum.***

- ***Epidermis:*** thin layer of living cells just below the stratum corneum. Its main function is to manufacture the stratum corneum. Epidermal cells are manufactured at the bottom layer, move upward as they mature, then ultimately become lifeless and part of the stratum corneum membrane. As the epidermis is made of "living cells", it cannot be dry. It is in the epidermis that pigment cells are present, producing the pigment **melanin.** Pigment provides protection from UV light (sunlight) penetration.

- Dermis: the deepest, thickest, strongest layer of skin. It is in the living dermis that we find collagen (originating from special cells called fibroblasts) and elastin fibers woven together, like a fine mantle. The dermis also houses nerves, blood vessels as well as sebaceous and sweat glands. As the dermis is inside the body, it also can never be dry. The dermis is able to repair and renew itself; yet very slowly. Therefore, **"dermis damage"**—caused by sunlight—can be permanent. With repeated exposure to sun over the years, the dermis becomes slowly destroyed; that is, sun penetrates through the stratum corneum and epidermis into the dermis, which does not have sufficient melanin pigment. Repeated sun exposure causes the dermis to lose its strength and resilience. It becomes weak and thin. The damaged dermis, caused by the sun, becomes *permanently wrinkled.* In summary, the much-abhorred wrinkles and deep lines our "faces" present to the world are caused by **sun damage over the years in the dermis.**

- **Subcutis:** joined to the bottom of the dermis, subcutaneous tissue is the deepest layer of the skin. This fatty layer cushions muscles, bones and internal organs against shocks. It acts as an insulator and stores energy.

The skin is "alive" with tissue, fluids, blood vessels, nerves and living cells (with about 95% of each cell comprised of water)—except for the very topmost layer, the **Stratum Corneum**. Although the top tissue-thin stratum corneum layer is lifeless, because the cells in it are remains of once-living epidermis cells, it is this topmost layer that plays a key role in the skin. **The Stratum Corneum is the barrier between us and the outside world.** It is "the face" we display for the world to see. The stratum corneum projects our life's experiences and expressions.

E. *ABC's of the Stratum Corneum*

a. The stratum corneum is a barrier. It prevents loss of tissue fluids and body chemicals and prevents substances coming in contact with the skin from entering it; e.g., pollutants, irritants, viruses, etc.
b. The stratum corneum is about 20 cell layers thick and is renewed constantly by the epidermis beneath. The entire stratum corneum is totally renewed and replaced every 3–4 weeks.
c. **The stratum corneum responds to water.** When it is kept moist, the stratum corneum is flexible and appears smooth and translucent to touch and sight.

Before we explore the relationship between the stratum corneum and water, let us first review woman's most feared facial foe—"the wrinkle".

F. *The Wrinkle*

The least understood, most feared skin concern voiced by American women is **the facial wrinkle**. What is it, how many, where do they come from . . . the questions are endless! Let's simplify:

- In the majority of cases, wrinkles are caused by **sun damage** and eventually **age**, and not by dryness. As previously stated, UV/UB rays damage the dermis. Sun damage over the years makes the dermis deteriorate and weaken, resulting in skin that is less resilient and "saggy". Wrinkle-causing sun damage starts as soon as sun starts to hit the skin. When enough sun damage accumulates, usually by adult life, wrinkles and deep lines start to appear. Once the dermis is sun-damaged, the condition is permanent.
- Cosmetic moisturizers, regardless of price, *do not penetrate into the skin deeper than the STRATUM CORNEUM*. While moisturizers can help soften and enhance the appearance of tiny lines and wrinkles, they cannot "unwrinkle" the more pronounced lines and wrinkles resulting from sun damage to the dermis. However, researchers have uncovered some recent evidence that certain compounds may be effective in helping to minimize wrinkles due to photoaging.

G. *The Role of Water: "Nature's Foundation of Youth"*

Dry skin is skin that lacks water in the stratum corneum. Since the epidermis and dermis are inside the body, they are always moist with bodily fluids, and therefore, are not subject to dryness. The stratum corneum, our "public face" is the only part of the skin's structure that can be dry.

When the stratum corneum is dry; i.e., dehydrated/lacking in water, it can feel tight and rough as well as flaky and dull in appearance. When the stratum corneum is dry, it can pull the skin into what will appear to be small, tiny lines.

There are several reasons why the stratum corneum becomes dry:

- With age, the stratum corneum becomes drier and loses its ability to retain water.
- The rate of cell turnover (of the living epidermis) slows down; thus the non-living stratum corneum cells remain on the skin's surface for a longer period of time—drying out more.
- The ability of the stratum corneum to retain water and of its cells and intercellular substance to hold together as one membrane vary among individuals.
- Oils produced by oil glands vary among individuals in amount and composition, and it is oil that coats the surface of the stratum corneum to retain water in it.

When the stratum corneum contains moisture, or water, the skin is flexible and smooth. Its cells plump up when moist, helping skin to look and feel softer and smoother.

While the stratum corneum needs water to be moist; oil can be used quite effectively as a moisturizing agent or as part of an ingredient complex and delivery system to help keep water in the stratum corneum. In fact, Topifram's patent-pending HRA Système™ enables all Topifram's new skin care formulas to be quickly absorbed into the stratum corneum without leaving a greasy after-feel. The Système™ utilizes a micro-emulsion combined with the latest concepts in liquid crystal technology to most effectively deliver and hold skin-softening moisture into the stratum corneum.

H. *Nature's Gift for Younger-Looking Skin*

Water is what the Stratum Corneum needs for the skin to stay smooth, flexible and young-looking. Caring for the skin requires delivering water to the stratum corneum, letting it soak into the stratum corneum cells to hydrate/moisturize and holding it there with a barrier to prevent the water from evaporating.

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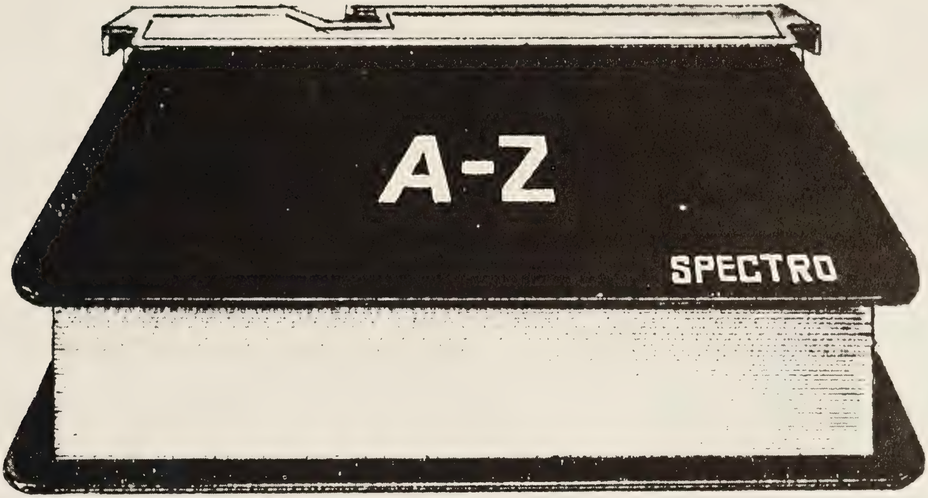

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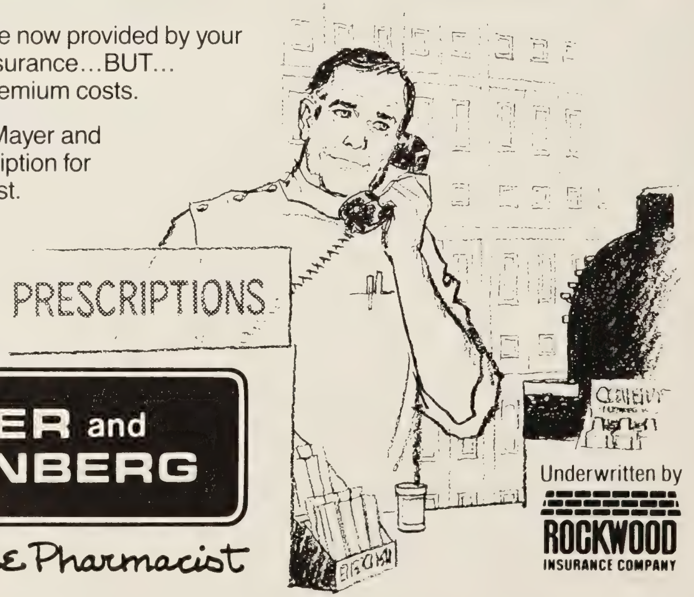

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107th Annual MPhA Convention
June 18–22, 1989
Sheraton Ocean City Resourt Hotel
Ocean City, Maryland

AN INVITATION

As President of MPhA this year as well as the Convention Chairman, it has been a great challenge to improve the Annual Convention. I think we've succeeded!

This year, convention attendees can earn 13.5 CE credits, nearly twice as many as in the past. Our business meeting has been reduced to one day to allow more time for education. In addition, we have redesigned our Trade Exposition to include luncheon with our exhibitors.

As for social events, along with the fun and feast of the Annual Crab and Chicken Feast we've included a 50's Sock Hop and Party so be sure to bring your saddle shoes and poodle skirts along for a great time.

Because I believe that the convention should be convenient to all, we have selected Monday, June 20 to be a perfect day for those who can only attend for one day. Why not come down on Sunday, enjoy a day at the beach and then earn 6 hours of CE on Monday?

I encourage every pharmacist in Maryland to attend the 107th Annual MPhA Convention. See you in OC!

Elwin Alpern, P.D.
MPhA President

PROGRAM

Sunday, June 18, 1989

12:00– 5:00 pm	Registration Opens
2:00– 5:00 pm	Wine and Cheese Reception
9:00–11:00 pm	Welcoming Cocktail Party

Monday, June 19, 1989

7:30– 8:30 am	Continental Breakfast
8:30–12:30 pm	Continuing Education Seminar *Changing Faces in Long Term Care —Some New Wrinkles* Part I
10:00–12:00 am	SAMPA Brunch and Fashion Show
12:30– 2:30 pm	Trade Exposition and Luncheon
2:30– 4:30 pm	Continuing Education Seminar *Medic Alert: Pharmacists Helping the Public*
6:30 pm	Crab and Chicken Feast Old Time Square Dance Hoe Down Berlin Fire Hall

Tuesday, June 20, 1989

7:30– 8:30 am	Continental Breakfast
8:30–12:30 pm	Continuing Education Seminar *Changing Faces in Long Term Care —Some New Wrinkles* Part II
10:00–12:00 am	SAMPA Breakfast and Seminar *Living with Arthritis*
12:30– 2:30 pm	Trade Exposition and Luncheon
2:30– 3:30 pm	Continuing Education Seminar *Extrinsic Asthma: The Role of the Pharmacist*
9:00–11:30 pm	Sock Hop and '50s Party

REGISTRATION

To register for the 107th Annual Convention of the Maryland Pharmacists Association, complete the registration form on the top portion of the back page of this brochure. Please print or type clearly. Return the form, with your check or money order for the total convention registration to the MPhA Offices.

Admission to all functions will be by ticket or badge. Pick up badges and other registration materials at the MPhA Registration Desk beginning Sunday, June 19 at 12:00 noon or on Monday, June 20 at 8:30 am. You must register with the MPhA to utilize special convention hotel rates. Spouses must register or purchase function tickets to attend any special functions.

Full MPhA or Spouse/Guest Registration includes all meetings and social events. Single Day registration includes all meetings and social events for that day only. Single Day registrants should indicate which day they plan to attend.

Registration Fees	*Before June 10*	*After June 10*
MPhA Member	$ 85.00	$ 95.00
Spouse/Guest	$ 75.00	$ 85.00
Non-member	$135.00	$145.00
Pharmacy Student	no charge	no charge
Children Under 18	no charge	no charge
Single Day	$ 40.00	$ 50.00
Crab and Chicken Feast		
Children Under 12	$ 8.50	$ 13.50
Extra Adult/Students	$ 17.50	$ 22.50
MPhA Annual Banquet		
Children Under 12	$ 17.00	$ 22.00
Extra Adult/Students	$ 22.00	$ 27.00
SAMPA Brunch	$ 10.00	$ 10.00
SAMPA Seminar	$ 10.00	$ 10.00

Wednesday, June 21, 1989

7:30– 8:30 am	Continental Breakfast
8:30–12:30 pm	MPhA House of Delegates Business Session
6:00– 7:00 pm	Cocktail Reception
7:00– 9:00 pm	MPhA Annual Awards and Installation Banquet

Thursday, June 22, 1989

9:00–12:30 pm	Simon Solomon Seminar *Diabetes Management— A Hands-on Approach*

CONTINUING EDUCATION

Changing Faces in Long Term Care—
Some New Wrinkles

Part I
Monday, June 19, 8:30 am–12:30 pm
Part II
Tuesday, June 20 8:30 am–12:30 pm

This two-part seminar will update pharmacists on the latest clinical, legislative, regulatory, and financial issues affecting long term care pharmacy. Focusing on ambulatory as well as institutional care of the elderly, this program will have information for all pharmacists.

Seminar speakers will include:

Deborah Wertheimer, M.D., a physician specializing in gerontology.
Beverly Baldwin, Ph.D., an expert on caregiver stress.
Janice MacGregor, Director of the Maryland Office on Aging Senior Outreach Program.
Peter Lamy, Ph.D., 1988 Remington Medalist, and Director of the UMAB Elder Care Program.

The Pharmacist and Medic Alert

Monday, June 19, 2:30–4:30 pm

Increasing public awareness of the Medic Alert system is the theme for this program. Speakers will be addressing the need for active pharmacist involvement in promoting this life-saving system

Extrinsic Asthma: The Role of the Pharmacist

Tuesday, June 20, 2:30–3:30 pm

Learn about how to help patients with extrinsic asthma through unique multi-media presentation. A video-tape with case examples will be followed by a question and answer session with an expert in pulmonary therapy. Pick up a self-study booklet to help earn even more continuing education credits.

Diabetes Management—A Hands On Approach
The Simon Solomon Lecture

Thursday, June 22, 9:00 am–12:30 pm

Looking at the role of pharmacists in diabetes care, this program will show how to assist diabetics in maintaining control of their disease, understanding the unique needs of the diabetic, and how to establish a diabetic care center in a community pharmacy.

Seminar speakers include:

Belinda Tilley, Pharm.D., clinical pharmacy coordinator at GBMC Hospital.
Carey Hillman, Ames Diagnostic Division representative.
and
A representive from the American Diabetes Association.

The Maryland Pharmacy Continuing Education Coordinating Council is approved by the American Council on Pharmaceutical Education as a provider of continuing education for pharmacists. The 107th Annual MPhA Convention enables an attendee to earn 13.5 contact hours (1.35 CEUs) of approved CE credit.

TRADE EXPOSITION

Keep up with the latest, most exciting developments and the newest products on the market at the MPhA Trade Exposition. Visit every exhibitor and be eligible to win a television!

Join us for lunch in the Exhibit Hall on Monday, June 19 and Tuesday, June 20 from 12:30 to 2:30 p.m.

1988 Exhibitors

Ayerst Laboratories
Bergen Brunswig Corporation
Boehringer Ingelheim
Bristol Laboratories
Burroughs-Wellcome Company
Ciba-Geigy Pharmaceuticals
District Photo, Inc.
Dista
The Drug House, Inc.
Food Plus
E. Fougera & Company
Geneva Generics, Inc.
Glaxo, Inc.
General Computer Corporation
Goldline Laboratories
Health Business Systems, Inc.
Hoechst-Roussel Pharmaceuticals
Key Pharmaceutical
Knoll Pharmaceuticals
Korff USA
Lederle Laboratories
Eli Lilly and Company
Lowey-District Wholesale Dru
Mayer & Steinberg
Marion Laboratories
Mead Johnson Pharmaceutic
Merck Sharp and Dohme
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E.R. Squibb & Sons, Inc.
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The Upjohn Company
3 PM, Inc./McKesson
Winthrop Laboratories
Wyeth Laboratories

ACCOMMODATIONS

Once again, the Maryland Pharmacists Association has been able to obtain for attendees discounted rates for one of Ocean City's finest resort hotels. In previous years, the hotel sold out of reserved rooms at the special MPhA convention rate. Don't be disappointed! Mail your reservation form *directly* to the hotel.

All room reservations must be received by the Sheraton **no later than Monday, May 15, 1989**. Otherwise, the Sheraton will be unable to guarantee space availability at these special rates.

Children under 17 stay free of charge *in same room* as parents. Rates are subject to 8 percent room tax. One night deposit is required. Full refund on 72 hours notice to hotel. Rooms are available for check-in at 3:00 p.m. The Sheraton Fontainebleu accepts personal checks *for deposit only.* No personal checks will be accepted after arrival. Credit cards are not accepted for advance deposit. A 72-hour cancellation or change notice is required.

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	Guest Rooms (per night)		
Single/Double	$115	Cabana Suites	$230
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With Maid Service	$900	Without Maid Service	$700

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City ______________ State ______________ Zip Code ______________

Nickname for Badge ______________ Phone ______________

Spouse/Guest Name ______________________________

Registration
(indicate number)

______ MPhA Member
______ Spouse/Guest
______ Non-Member
______ Pharmacy Student
______ Children Under 18
______ Single Day

Special Functions
(indicate number)

Crab & Chicken Feast

______ Children Under 12
______ Extra Adult/Students

MPhA Annual Banquet

______ Children Under 12
______ Extra Adult/Students

Return top portion to MPhA, 650 West Lombard Street, Baltimore, MD 21201

- -

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Analysis of Supportive Pharmacy Personnel Survey

Distributed in October 1988

The following is a summary of the Pharmacy Supportive Personnel Task Force survey that was distributed to all MPhA members in October. More than 25 percent of all MPhA members sent in responses. The Task Force will now begin formulating policy resolutions to present to the MPhA House of Delegates Meeting on June 21, 1989 at the Annual Convention.

1) How long have you been a pharmacist?
(321 responses)
76.3% a. less than 10 years
23.6% b. 10 years or more

2) What is your practice setting?
(323 responses)
61% a. Independent community pharmacy
14% b. Chain pharmacy
16% c. Hospital pharmacy
3% d. Nursing home pharmacy services
0.3% e. Consultant pharmacy services
0.3% f. Pharmacy education
5% g. Other—HMOs, Retired

3) What is your position?
(321 responses)
68.5% a. Administrator or owner
36.4% b. Staff or employee pharmacist

4) How many prescription orders does your pharmacy fill per day?
(318 responses)
63.8% a. Less than 150
36.2% b. 150 or more

5) How many hours is your pharmacy open per week?
(322 responses)
13.6% a. Less than 50 hours
53.1% b. Between 51–75 hours
33.2% c. More than 75 hours

6) Do you utilize supportive pharmacy personnel?
(322 responses)
79.5% a. Yes
20.5% b. No (if no, go to question #14)

7) How many 'pill-counting' machines does your pharmacy have?
(268 responses)
73.1% a. none
25% b. 1–2
1.8% c. more than 2

8) Does your pharmacy use a computer for prescription dispensing services?
(267 responses)
22.4% a. No
77.5% b. Yes

9) In what capacity do you use pharmacy supportive personnel with regard to dispensing functions?
(check all that apply)
__ Type prescription labels
__ Receive telephone prescription orders
__ Enter prescriptions into computer
__ Prepare prescriptions (count, pour, fill carts, etc)
__ Prepare parenteral medications
__ Delivery of prescription orders
__ Prefill unit-dose or unit-of-use
__ Other functions (specify: ____)

Pharmacists responded that supportive personnel were used for most of the choices listed above in many different practice settings.

10) How many pharmacists are actively involved in direct supervision of supportive personnel?
(255 responses)
57.6% a. 1 pharmacist for every supportive personnel
30.6% b. 1 pharmacist per 2 supportive personnel
7.6% c. 1 pharmacist per 3 supportive personnel
2.8% d. 1 pharmacist per 4 supportive personnel
1.9% e. 1 pharmacist per more than 4 supportive personnel

11) For the most part, what is the highest level of education your pharmacy supportive personnel have?
(261 responses)
4.9% a. Some high school
57.8% b. High school diploma or equivalent
37.2% c. Some college or vocational school

12) How are your pharmacy supportive personnel trained?
(261 responses)
18.0% a. Formal training program within your facility
81.2% b. On-the-job, informal training
0.8% c. Formal training program outside your facility (e.g., community college)

13) Do you have a written policy and procedures manual that includes the use of pharmacy supportive personnel?
(260 responses)
63.8% a. No
36.1% b. Yes

14) How difficult is it to recruit pharmacy supportive personnel?
(258 responses)
22.4% a. Not difficult at all
59.7% b. Somewhat difficult
17.8% c. Very difficult

15) How difficult is it to recruit pharmacists?
(260 responses)
9.6% a. Not difficult at all
43.8% b. Somewhat difficult
46.5% c. Very difficult

16) Approximately what do you pay your pharmacy supportive personnel?
(257 responses)

2.7%	a. less than $4/hour
45.1%	b. $4–$5.99/hour
44.3%	c. $6–$7.99/hour
7.7%	d. $8/hour or more

17) Are you in favor of recognizing pharmacy supportive personnel through certification (i.e., a voluntary program that sets minimum competencies for pharmacy supportive personnel)
(322 responses)

GENERAL RESPONSES

54.3%	a. Yes
45.6%	b. No

YEARS IN PRACTICE RESPONSES

16.6%	a. Yes and less than 10 years
35.8%	b. No and less than 10 years
37.5%	a. Yes and more than 10 years
38.7%	b. No and more than 10 years

EMPLOYMENT POSITION RESPONSES

33.4%	a. Yes and owner/manager
45.6%	b. No and owner/manager
20.9%	c. Yes and staff pharmacist
10.6%	d. No and staff pharmacist

SUPPORT PERSONNEL UTILIZER RESPONSES

43.6%	a. Yes and use supportive personnel
35.8%	b. No and use supportive personnel
10.9%	a. Yes and don't use supportive
9.6%	b. No and don't use supportive

IN FAVOR OF CERTIFICATION BY PRACTICE SIGHT

48.3%	a. Independent community pharmacy
15.3%	b. Chain pharmacy
24.4%	c. Hospital pharmacy
3.9%	d. Nursing home pharmacy services
0.6%	e. Consultant pharmacy services
0.6%	f. Pharmacy education
6.3%	g. Other—HMOs, Retired

OPPOSE CERTIFICATION BY PRACTICE SITE

75.5%	a. Independent community pharmacy
12.2%	b. Chain pharmacy
6.1%	c. Hospital pharmacy
2.7%	d. Nursing home pharmacy services
0.0%	e. Consultant pharmacy services
0.0%	f. Pharmacy education
3.4%	g. Other—HMOs, Retired

18) Are you in favor of recognizing pharmacy supportive personnel through licensure (i.e., a mandatory program which requires pharmacy supportive personnel to meet minimum competencies)?
(321 responses)

28.9%	a. Yes
71.0%	b. No

YEARS IN PRACTICE RESPONSES

7.8%	a. Yes and less than 10 years
21.0%	b. No and less than 10 years
16.0%	a. Yes and more than 10 years
55.2%	b. No and more than 10 years

EMPLOYMENT POSITION RESPONSES

19.7%	a. Yes and owner/manager
9.4%	b. No and owner/manager
48.6%	c. Yes and staff pharmacist
22.3%	d. No and staff pharmacist

SUPPORT PERSONNEL UTILIZER RESPONSES

21.3%	a. Yes and use supportive personnel
7.8%	b. No and use supportive personnel
58.1%	a. Yes and don't use supportive
12.8%	b. No and don't use supportive

IN FAVOR OF LICENSURE BY PRACTICE SIGHT

57.0%	a. Independent community pharmacy
15.0%	b. Chain pharmacy
19.3%	c. Hospital pharmacy
4.3%	d. Nursing home pharmacy services
0.0%	e. Consultant pharmacy services
1.0%	f. Pharmacy education
3.2%	g. Other—HMOs, Retired

OPPOSE LICENSURE BY PRACTICE SITE

62.6%	a. Independent community pharmacy
13.6%	b. Chain pharmacy
14.9%	c. Hospital pharmacy
3.0%	d. Nursing home pharmacy services
0.4%	e. Consultant pharmacy services
0.0%	f. Pharmacy education
5.7%	g. Other—HMOs, Retired

19) Do you feel there is a need for additional educational programs for pharmacy supportive personnel?
(317 responses)

GENERAL RESPONSES

56.8%	a. Yes
43.2%	b. No

DIFFICULTY IN FINDING SUPPORT RESPONSES

9.1%	a. Yes and not difficult to find
13.0%	b. No and not difficult to find
37.6%	a. Yes and somewhat difficult
23.3%	b. No and somewhat difficult
9.5%	a. No and very difficult
7.5%	b. No and very difficult

20) What impact do you think that pharmacy supportive personnel have on employment of pharmacists?
(316 responses)

GENERAL RESPONSES

57.2%	a. No impact
38.3%	b. Decreases the available jobs for pharmacists
4.4%	c. Increases the available jobs for pharmacists

OWNER/MANAGER RESPONSES

59.5%	a. No impact
35.8%	b. Decreases the available jobs for pharmacists
4.6%	c. Increases the available jobs for pharmacists

EMPLOYEE RESPONSES

53.5%	a. No impact
42.4%	b. Decreases the available jobs for pharmacists
4.0%	c. Increases the available jobs for pharmacists

IN FAVOR OF CERTIFICATES OR EDUCATION RESPONSES

58.5%	a. No impact
35.5%	b. Decreases the available jobs for pharmacists
6.0%	c. Increases the available jobs for pharmacists

21) What impact do you think that pharmacy supportive personnel have on the profession of pharmacy? (315 responses)

GENERAL RESPONSES

26.4%	a. No impact
23.5%	b. Decreases professional opportunities for pharmacists
50.2%	c. Increases professional opportunities for pharmacists

OWNER/MANAGERS

28.8%	a. No impact
22.3%	b. Decreases professional opportunities for pharmacists
48.8%	c. Increases professional opportunities for pharmacists

EMPLOYEE PHARMACISTS

21.4%	a. No impact
25.5%	b. Decreases professional opportunities for pharmacists
53.0%	c. Increases professional opportunities for pharmacists

calendar

April 2	Seminar: Update on Hyperlipidemia
April 8–12	APhA Annual Convention, Anaheim
April 10	UM School of Pharmacy Breakfast, APhA
April 16	AZO Breakfast and CE Program
May 4	AZP/CECC Fritz Berman Seminar
June 1	MSHP Monthly Meeting: Johns Hopkins
June 4–8	ASHP Annual Convention, Nashville
June 18–22	107th MPhA Annual Convention

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Drug Utilization Review

by Gary Theilman, DUR PEP Student

Drug Utilization Review (DUR) is not confined to hospitals, HMO's and other "closed" practice situations. Many pharmacy associations manage DUR programs which involve the entire state. In Maryland, the Department of Health and Mental Hygiene has a contract with the Maryland Pharmacists Association to provide DUR services for all Medicaid recipients. By reviewing Medicaid claims data, MPhA helps to reduce costs due to inappropriate medication utilization and increased risk of drug induced illnesses.

Health Information Designs (HID) is a subcontractor for MPhA that processes the Medicaid claims data through a computer program called "DURbase". DURbase sorts through the thousands of patients Medicaid serves and picks out those whose profiles indicate a possible problem. For example, a patient who is receiving both Aldactone and a potassium supplement would be tagged as "high risk" by the computer. DURbase also checks for possible disease-drug interactions such as the patient with epilepsy who is receiving Haldol. Each month, MPhA receives the profiles of the patients that DURbase has tagged as "high risk". These profiles are then distributed to review committees throughout Maryland. These committees are made up of pharmacists and physicians who are familiar with the prescribing practices in their particular part of the state. Members of these committees review the "high-risk" profiles and decide whether the situation needs to be brought to the attention of the physicians and pharmacies involved. In addition to the critieria used by the computer, committee members also look for such things as long intervals between refills (possibly indicating noncompliance) and the use of multiple physicians and pharmacies. The providers are contacted by mail, and files are maintained on each patient for possible follow-up. The response of providers to the program has been overwhelmingly positive; more than 94 percent indicated the the program is a help to them.

TABLE 1
States that have Drug Utilization Review Programs in place

State	Administrator
Arkansas	Arkansas Pharmacist Association
Florida	Florida Pharmacy Association
Iowa	Iowa Pharmacists Association
Kansas	Kansas Pharmacists Association
Kentucky	State Medicaid Program
Maryland	Maryland Pharmacists Association
Maine	State Medicaid Program
Michigan	State Medicaid Program
Minnesota	State Medicaid Program
Missouri	State Medicaid Program
Mississippi	Mississippi Pharmacists Association
North Dakota	Medical Services Department
Nebraska	Nebraska Pharmacists Association
Ohio	State Medicaid Program
Oregon	Oregon Pharmacists Association
South Carolina	State Medicaid Program
Vermont	State Medicaid Program
Washington State	State Medicaid Program
Wisconsin	University of Wisconsin

TABLE 2
States that have plans to implement a Drug Utilization Review Program

Alabama
California
Georgia
Massachusetts
New Jersey
Nevada
New York
Rhode Island
South Dakota
Tennessee
Virginia
West Virginia
Wyoming

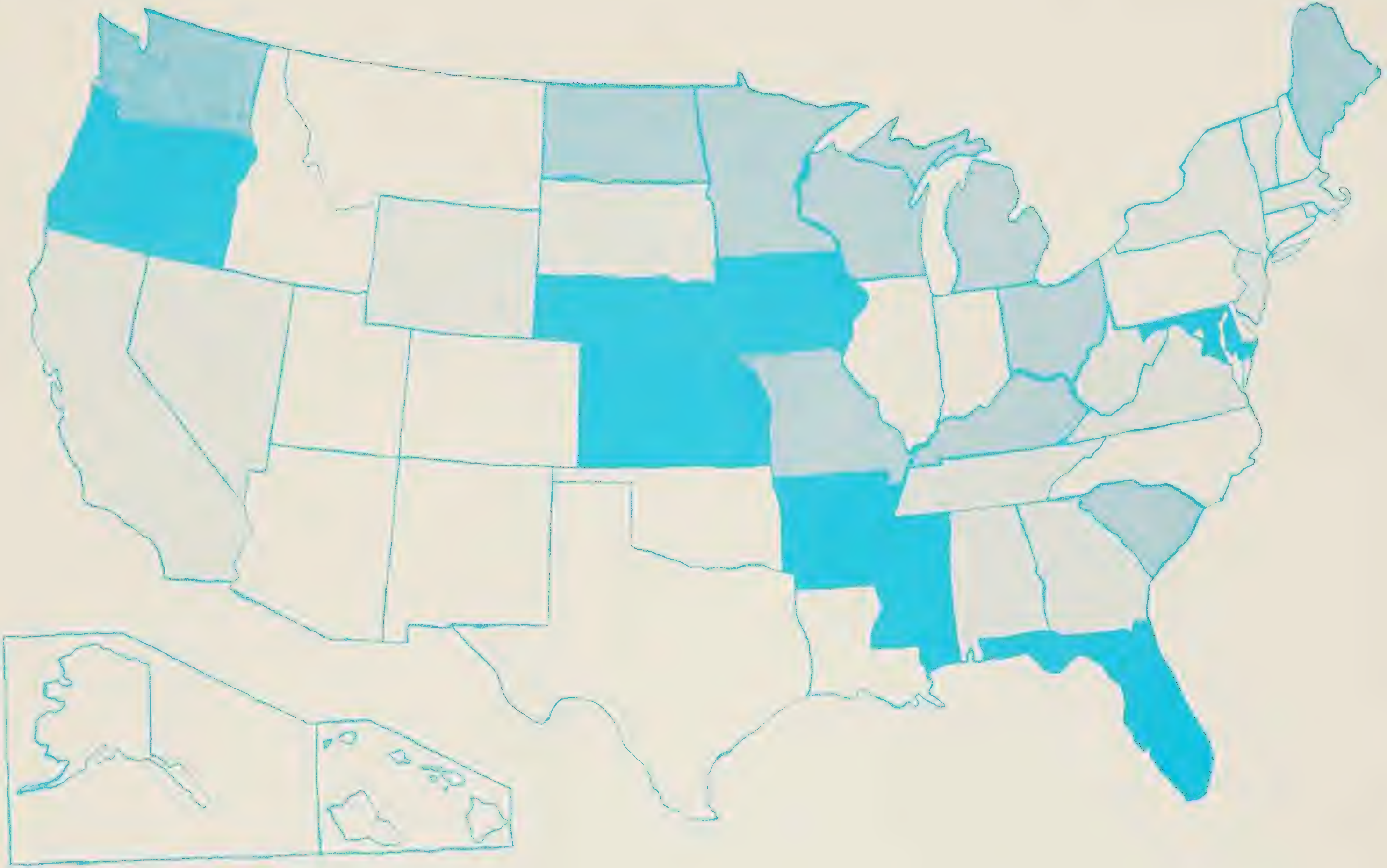
A survey was conducted of state pharmacy associations to determine which states have drug utilization programs like the one in Maryland. The survey also asked if the program was administered by the state association. Fifty-two survey forms were sent out to the states, the District of Columbia, and Puerto Rico. Thirty-seven were returned by the deadline. The remaining associations were contacted by phone. Nineteen states now have programs in place, with eight of these programs administered by the state pharmacy association (Table I). Thirteen other states have plans to implement a DUR program (Table II).

Participation in Drug Utilization Review is just one of the ways that pharmacists can be recognized for what they are: medication specialists. Pharmacy associations, by administering or contributing to these programs not only serves its members, but the whole health care community.

Special thanks to Bethany Baker, M.L.S. for preparing the map.

■ ▨ □

Key To Map
Dark States With DUR Programs Administered by the State Pharmacy Association.
Medium States with DUR Programs Not Administered by the State Pharmacy Association
Light States That Plan to Implement a Drug Utilization Review Program



SeniorReach

NATIONAL VOLUNTEER WEEK, APRIL 9–15, 1989

Did you know that nearly one-half of all Americans over the age of thirteen volunteer annually? They contribute their time, energy and talents to help others. America has a long history of people helping others—from the days of quilting bees and barn raisings.

People of all ages can be volunteers. According to the American Association of Retired Persons, more than 30 percent of Americans over 55 do volunteer work. The dollar value of those who volunteer is estimated at more than $110 billion annually.

When asked why they became volunteers, some reply that they want to help others, and they want to keep busy. But most say that they get a lot of satisfaction helping others.

A recent study by Better Homes and Gardens readers indicates that volunteering has very positive effects. After helping others, nearly 70 percent of the respondents reported that they had a sense of calmness, a reduction of stress and a better feeling about themselves. These health benefits suggest that volunteering may indeed be good for you.

The opportunities for volunteering are practically endless. You can work alone, with a neighborhood group, or in an organization. Associations, hospitals, nursing homes, hospices, schools, political organizations, social services and community programs always need volunteers. Often, you can work near your home at the hours that are most convenient for you.

In our own state, more than two million Marylanders volunteer each year. Governor Schaefer is especially committed to volunteerism and to identifying those individuals and groups who have made outstanding contributions. At a recognition ceremony last year he said, "In education, social services and aging, in hospitals and nursing homes; everywhere there are volunteers who make a difference in the live of Marylanders."

Help celebrate National Volunteer Week during April 9–15, 1989. Become a volunteer! If you are interested in learning more about volunteer opportunities in the state, contact:

The Governor's Office on Volunteerism
301 W. Preston Street, Room 1506A
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WARNINGS Status asthmaticus should be considered a medical emergency and is defined as that degree of bronchospasm which is not rapidly responsive to usual doses of conventional bronchodilators Optimal therapy for such patients frequently requires both *additional medication*, parenterally administered, and *close monitoring*, preferably in an intensive care setting

Although increasing the dose of theophylline may bring about relief, such treatment may be associated with toxicity The likelihood of such toxicity developing increases significantly when the serum theophylline concentration exceeds 20 mcg/ml Therefore, determination of serum theophylline levels is recommended to assure maximal benefit without excessive risk

Serum levels above 20 mcg/ml are rarely found after appropriate administration of recommended doses However, in individuals in whom theophylline plasma clearance is reduced *for any reason*, even conventional doses may result in increased serum levels and potential toxicity Reduced theophylline clearance has been documented in the following readily identifiable groups 1) patients with impaired renal or liver function, 2) patients over 55 years of age, particularly males and those with chronic lung disease, 3) those with cardiac failure from any cause, 4) neonates, and 5) those patients taking certain drugs (macrolide antibiotics and cimetidine) Decreased clearance of theophylline may be associated with either influenza immunization or active infection with influenza

Reduction of dosage and laboratory monitoring is especially appropriate in the above individuals Less serious signs of theophylline toxicity (i.e. nausea and restlessness) may occur frequently when initiating therapy, but are usually transient, when such signs are persistent during maintenance therapy, they are often associated with serum concentrations above 20 mcg/ml Unfortunately, however, serious side effects such as ventricular arrhythmias, convulsions or even death may appear as the first sign of toxicity without any previous warning Stated differently *serious toxicity is not reliably preceded by less severe side effects*

Many patients who require theophylline may exhibit tachycardia due to their underlying disease process so that the cause/effect relationship to elevated serum theophylline concentrations may not be appreciated

Theophylline products may cause dysrhythmia and/or worsen pre-existing arrhythmias and any significant change in rate and/or rhythm warrants monitoring and further investigation

The occurrence of arrhythmias and sudden death (with histological evidence of necrosis of the myocardium) has been recorded in laboratory animals (minipigs, rodents and dogs) when theophylline and beta agonists were administered concomitantly, although not when either was administered alone The significance of these findings when applied to human usage is currently unknown

PRECAUTIONS THEO-DUR TABLETS SHOULD NOT BE CHEWED OR CRUSHED

General Theophylline half-life is shorter in smokers than in non-smokers Therefore, smokers may require larger or more frequent doses Morphine and curare should be used with caution in patients with airway obstruction as they may suppress respiration and stimulate histamine release Alternative drugs should be used when possible Theophylline should not be administered concurrently with other xanthine medications Use with caution in patients with severe cardiac disease, severe hypoxemia, hypertension, hyperthyroidism, acute myocardial injury, cor pulmonale, congestive heart failure, liver disease, in the elderly (especially males) and in neonates In particular, great caution should be used in giving theophylline to patients with congestive heart failure Frequently, such patients have markedly prolonged theophylline serum levels with theophylline persisting in serum for long periods following discontinuation of the drug. Individuals who are rapid metabolizers of theophylline, such as the young, smokers, and some non-smoking adults, may not be suitable candidates for once-daily dosing. These individuals will generally need to be dosed at 12 hour or sometimes 8 hour intervals. Such patients may exhibit symptoms of bronchospasm near the end of a dosing interval, or may have wider peak-to-trough differences than desired

Use theophylline cautiously in patients with history of peptic ulcer. Theophylline may occasionally act as a local irritant to the G I. tract although gastrointestinal symptoms are more commonly centrally mediated and associated with serum drug concentrations over 20 mcg/ml

Information for Patients The physician should reinforce the importance of taking only the prescribed dose and time interval between doses. THEO-DUR tablets should not be chewed or crushed When dosing THEO-DUR on a once daily (q24h) basis, tablets should be taken whole and not split As with any controlled-release theophylline product, the patient should alert the physician if symptoms occur repeatedly, especially near the end of the dosing interval

DRUG INTERACTIONS Drug-Drug Toxic synergism with ephedrine has been documented and may occur with some other sympathomimetic bronchodilators In addition, the following drug interactions have been demonstrated

Drug	**Effect**
Theophylline with lithium carbonate	Increased excretion of lithium carbonate
Theophylline with propranolol	Antagonism of propranolol effect
Theophylline with cimetidine	Increased theophylline blood levels
Theophylline with troleandomycin, erythromycin	Increased theophylline blood levels

Drug-Food *THEO-DUR 100 mg Sustained Action Tablets* have not been adequately studied to determine whether their bioavailability is altered when given with food Available data suggest that drug administration at the time of food ingestion may influence the absorption characteristics of theophylline controlled-release products resulting in serum values different from those found after administration in the fasting state

A drug-food effect, if any, would likely have its greatest clinical significance when high theophylline serum levels are being maintained and/or when large single doses (greater than 13 mg/kg or 900 mg) of a controlled-release theophylline product are given

THEO-DUR (200, 300, and 450 mg) Sustained Action Tablets The rate and extent of absorption of theophylline from THEO-DUR 200 mg, 300 mg, and 450 mg tablets when administered fasting or immediately after a moderately high fat content breakfast is similar

Drug-Laboratory Test Interactions When plasma levels of theophylline are measured by spectrophotometric methods, coffee, tea, cola beverages, chocolate, and acetaminophen contribute falsely high values

Carcinogenesis, Mutagenesis, and Impairment of Fertility Long-term animal studies have not been performed to evaluate the carcinogenic potential, mutagenic potential, or the effect on fertility of xanthine compounds

Pregnancy Category C—Animal reproduction studies have not been conducted with theophylline It is not known whether theophylline can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity Xanthines should be given to a pregnant woman only if clearly needed

Nursing Mothers It has been reported that theophylline distributes readily into breast milk and may cause adverse effects in the infant. Caution must be used if prescribing xanthine to a mother who is nursing, taking into account the risk-benefit of this therapy

Pediatric Use Safety and effectiveness of THEO-DUR administered
1 Every 24 hours in children under 12 years of age, have not been established
2 Every 12 hours in children under 6 years of age, have not been established

ADVERSE REACTIONS The most consistent adverse reactions are usually due to overdose and are
1 *Gastrointestinal* nausea, vomiting, epigastric pain, hematemesis, diarrhea
2. *Central nervous system.* headaches, irritability, restlessness, insomnia, reflex hyperexcitability, muscle twitching clonic and tonic generalized convulsions
3 *Cardiovascular* palpitation, tachycardia, extrasystoles, flushing, hypotension, circulatory failure, ventricular arrhythmias
4 *Respiratory* tachypnea
5 *Renal* albuminuria, increased excretion of renal tubular and red blood cells, potentiation of diuresis
6 *Other* rash, hyperglycemia and inappropriate ADH syndrome

OVERDOSAGE Management If potential oral overdose is established and seizure has not occurred
A Induce vomiting
B Administer a cathartic (this is particularly important if sustained-release preparations have been taken)
C Administer activated charcoa
if patient is having a seizure
A Establish an airway
B Administer oxygen
C Treat the seizure with intravenous diazepam, 0 1 to 0.3 mg/kg up to 10 mg
D Monitor vital signs, maintain blood pressure and provide adequate hydration

Post Seizure Coma
A Maintain airway and oxygenation
B If a result of oral medication, follow above recommendations to prevent absorption of the drug, but intubation and lavage will have to be performed instead of inducing emesis, and the cathartic and charcoal will need to be introduced via a large bore gastric lavage tube
C Continue to provide full supportive care and adequate hydration while waiting for drug to be metabolized In general, the drug is metabolized sufficiently rapid so as not to warrant consideration of dialysis, however, if serum levels exceed 50 mcg/ml charcoal hemoperfusion may be indicated

CAUTION Federal law prohibits dispensing without prescription For full prescribing information, see package insert
Revised 6/87

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Review of 1984–1987 Hospital Pharmacy Operations

James R. Talley, M.S.
School of Pharmacy
Northeast Louisiana University
Monroe, LA 71209-0470

This review of 1984–1987 hospital pharmacy operations was abstracted from editions of the *Lilly Hospital Pharmacy Survey*. Table 1 lists summary information for the years 1984–1987. The average hospital has had a reduction of 5.3% beds (13 beds) since 1984 with a census decrease of 2%. The average census has been falling consistently since 1982 and is approximately 12% less than the average 73% average rate observed from 1975–1981.

The average length of patient stay reversed a declining trend established in prior years; and increased to 6.9 days in 1987 as comparied to 6.0 days in 1986 which represented a 9.1% decrease since 1984. The number of hours the central pharmacy was open slightly declined in 1987, from 97 hours in 1986 to 95 hours in 1987; compared to the 1984 figure of 97 hours. The hours worked by pharmacists declined 1.4% in 1987; while hours worked by technicians, and support

TABLE 1
Average hospital pharmacy (general private nonprofit)

	1984	1986	1987	Change 1985–86	Change 1986–87	Change 1984–87
Bed capacity	245	235	232	−3.8%	−1.3%	−5.3%
Census (occupied beds)	63%	59%	61%			
Admissions	8,582	8,416	7,404	−1.8%	−12.1%	−13.7%
Patient days	56,338	50,607	51,547	−5.3%	+1.9%	−9.5%
Length of patient stay (days)	6.6	6.0	6.9			
Hours central pharmacy open/week	97	97	95	−3.1%	−2.1%	−2.1%
Pharmacist hours/week	290	294	290	−5.1%	−1.4%	0%
(FTE)	(7.3)	(7.3)	(7.2)			
Technician hours/week	260	268	274	−3.0%	+2.2%	+5.4%
(FTE)	(6.5)	(6.7)	(6.9)			
Support personnel hours/week	109	115	123	+0.9%	+6.9%	+12.8%
(FTE)	(2.7)	(2.9)	(3.1)			
Inventory	$121,414	$120,397	$151,517	−0.7%	+25.8%	+24.8%
/patient day	$2.16	$2.38	$2.93	+4.8%	+23.1%	+35.7%
/bed	$498	$512	$653	+3.0%	+27.5%	+31.1%
/occupied bed	$786	$868	$1,071	+4.8%	+23.4%	+36.7%
/admission	$14.15	$14.31	$20.46	+1.1%	+43.0%	+44.6%
Purchases	$944,569	$1,053,737	$1,217,565	+2.0%	+15.5%	+28.9%
/patient day	$16.77	$20.82	$23.62	+7.7%	+13.5%	+40.9%
/bed	$3,855	$4,484	$5,248	+5.9%	+17.0%	+36.1%
/occupied bed	$6,118	$7,600	$8,603	+7.7%	+13.2%	+40.6%
/admission	$110.06	$125.21	$164.45	+3.8%	+31.3%	+49.4%
Inventory turnover rate	7.8	8.7	8.0			
Floor area central pharmacy (square feet)	1734	1712	1737			

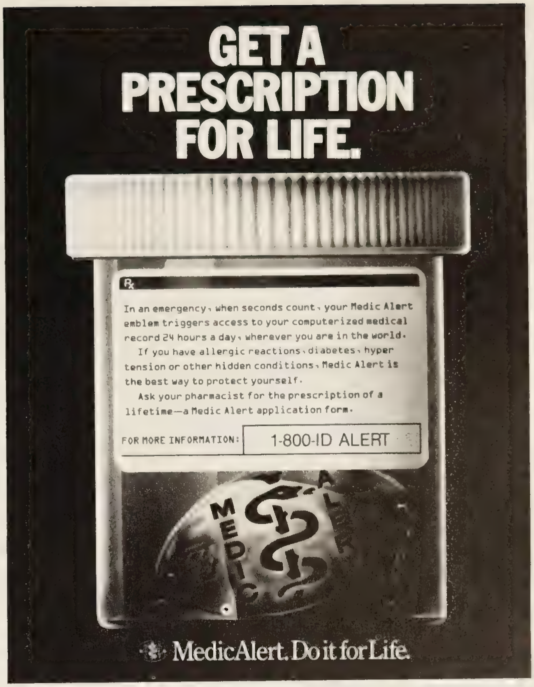
personnel slightly increased in 1987 (+2.2% & +6.9%).

In 1987, total inventory showed a marked increase from $120,397 in 1986 to $151,517 in 1987 (+25.8%). Inventory based on per patient day (+23.1%), per bed (+27.5%), per occupied bed (+23.4%), and per admission (+43.0%) all increased. As would be expected, purchases increased for all of these categories (+13.5%, +17.0%, +13.2%, & +31.3%). Reversing a trend of several years, the inventory turnover rate decreased and was 8.0 in 1987; as compared to 8.7 in 1986.

TABLE 2
Over 85% of Hospital Pharmacies offered the following services:

	1986	1987
Monitoring patient profiles	94.4%	94.2%
Monitoring drug interactions	91.2%	90.6%
Drug utilization review	91.8%	90.6%
In-service education	88.5%	86.7%

The ranking of services provided by pharmacy departments changed little from 1986 to 1987 (see Table 2). However, in 1985 these services were offered by over 70% of pharmacies comparied to 1987 where they were offered by over 85% of pharmacies.



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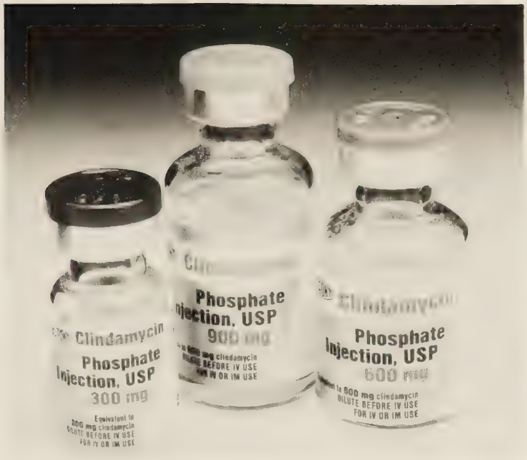
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Stuart Pharmaceuticals has introduced a once daily angiotensin converting enzyme inhibitor/diuretic combination called Zestoretic. Two strengths are available 20 mg/25 mg and 20 mg/12.5 mg.

The chronic skin condition called rosacea, characterized by the bulbous red nose of W. C. Fields, can now be effectively treated with a new prescription therapy MetroGel, developed by Curatek Pharmaceuticals.

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Continuing Education Quiz

The Maryland Pharmacist **APRIL 1989**

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by July 1, 1989. A continuing education certificate for one contact credit) will be mailed to you within 30 days. Please type or print clearly.

Name ______________________________

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Is this program used to meet your mandatory CE? [ ] Yes [ ] No

Did this article achieve its stated objectives? [ ] Yes [ ] No

How long did it take you to complete the program? ____________ minutes

ASA in Coronary Heart Disease

1. Which of the following is considered to be the single most preventable cause of cardiovascular morbidity in the U.S.?
   a. Cigarette smoking
   b. Hyperlipidemia
   c. Hypertension
   d. Obesity

2. Antithrombic agents are employed primarily to treat:
   a. arterial thrombic disorders.
   b. venous thrombic disorders.

3. The major cause of occlusion in the coronary arteries is:
   a. ventricular fibrillation resulting from A/V nodal block.
   b. excessive ischemia due to severe anginal attacks.
   c. vascular spasms after overstimulation by the vasomotor center.
   d. thrombi that embolize and lodge in coronary blood vessels.

4. All of the following are appropriate points of information for counseling consumers on the use of aspirin to reduce the risk of myocardial infarction EXCEPT:
   a. "Each dose should be taken with a glass of fluid or a light snack."
   b. "Check with your doctor before deciding to begin this use."
   c. "All forms of salicylate derivatives are equally effective."
   d. "Keep the bottle tightly closed to protect the tablets from deterioration."

5. Which of the following represents the estimated number of Americans who experience heart attacks each year?
   a. 750,000
   b. 1,500,000
   c. 2,500,000
   d. 5,000,000

6. Aspirin is believed to convey its antithrombotic activity by inhibiting the enzyme:
   a. cyclo-oxygenase.
   b. monoamine oxidase.
   c. prostacyclinase.
   d. thromboxenase.

7. The chemical that is the substrate of the enzyme described in question #6 above, and which is metabolized to prostaglandins is:
   a. arachidonic acid.
   b. lactic acid.
   c. prostaglandic acid.
   d. uric acid.

8. All of the following statements are true EXCEPT:
   a. aspirin is approved for physician-supervised use to lower the risk of myocardial infarction.
   b. aspirin is indicated for prescribed use to reduce the risk of recurrent transient ischemic attacks in men.
   c. aspirin decreases the chance for morbidity and premature death from certain cardiovascular diseases.
   d. aspirin is indicated for self-therapy in decreasing the risk of death in persons with previous myocardial infarction.

9. The substance that is a potent stimulator of platelet aggregation and causes vasoconstriction is:
   a. prostacyclin.
   b. thromboxane.

10. Anticoagulant drugs are employed primarily to treat:
    a. arterial thrombic disorders.
    b. venous thrombic disorders.

Classified

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

PHARMACY RX ITEMS, broken containers, fast and medium movers for sale at reduced prices. Contact Preston Pharmacy at (301) 673-2318. Pharmacist closing store.

PHARMACY COMPUTER System for sale. 3PM 40/40, 5 years old, Best offer. Call Brian at Penn-Dol, (301) 669-2424.

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PHARMACY FOR SALE. Well-established pharmacy on Eastern Shore of Maryland. Great hunting and fishing, close to beaches. $420,000 volume, 87% prescription and OTC. Call (301) 957-1648 after 8 pm.

PHARMACISTS REHABILITATION COMMITTEE HOTLINE is (301) 727-0746.

FDA HOTLINE FOR AIDS information is 800-432-AIDS.

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WANTED Futuro flannel lined incontinence pants, size medium. Call Professional Pharmacy (301) 655-2060.

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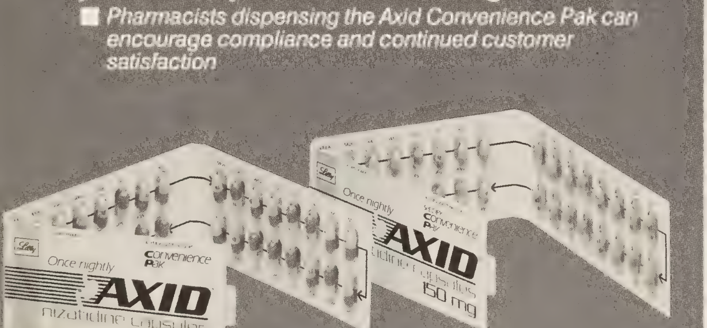

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Brief Summary

Consult the package literature for complete information.

Indications and Usage: Axid is indicated for up to eight weeks for the treatment of active duodenal ulcer. In most patients, the ulcer will heal within four weeks.

Axid is indicated for maintenance therapy for duodenal ulcer patients at a reduced dosage of 150 mg h.s. after healing of an active duodenal ulcer. The consequences of continuous therapy with Axid for longer than one year are not known

Contraindication: Axid is contraindicated in patients with known hypersensitivity to the drug and should be used with caution in patients with hypersensitivity to other H_2-receptor antagonists

Precautions: *General* – 1. Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy

2. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver. In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects.

Laboratory Tests – False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine

Drug Interactions – No interactions have been observed between Axid and theophylline, chlordiazepoxide, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently

Carcinogenesis, Mutagenesis, Impairment of Fertility – A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice, although hyperplastic nodules of the liver were increased in the high-dose males as compared with placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high-dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement as compared with concurrent controls and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery are not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, mouse lymphoma assay, chromosome aberration tests, and a micronucleus test

In a two-generation, perinatal and postnatal fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy – Teratogenic Effects – Pregnancy Category C – Oral reproduction studies in rats at doses up to 300 times the human dose and in Dutch Belted rabbits at doses up to 55 times the human dose revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers – Studies conducted in lactating women have shown that <0.1% of the administered oral dose of nizatidine is secreted in human milk in proportion to plasma concentrations. Caution should be exercised when administering nizatidine to a nursing mother.

Pediatric Use – Safety and effectiveness in children have not been established

Use in Elderly Patients – Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among reported adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs < 0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to determine whether these were caused by nizatidine.

Hepatic – Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients and was possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L) and, in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular – In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

CNS – Rare cases of reversible mental confusion have been reported

Endocrine – Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic – Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H_2-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported.

Integumental – Sweating and urticaria were reported significantly more frequently in nizatidine- than in placebo-treated patients Rash and exfoliative dermatitis were also reported.

Hypersensitivity – As with other H_2-receptor antagonists, rare cases of anaphylaxis following administration of nizatidine have been reported. Because cross-sensitivity in this class of compounds has been observed, H_2-receptor antagonists should not be administered to individuals with a history of previous hypersensitivity to these agents. Rare episodes of hypersensitivity reactions (eg, bronchospasm, laryngeal edema, rash, and eosinophilia) have been reported

Other – Hyperuricemia unassociated with gout or nephrolithiasis was reported Eosinophilia, fever, and nausea related to nizatidine administration have been reported.

Overdosage: Overdoses of Axid have been reported rarely. The following is provided to serve as a guide should such an overdose be encountered

Signs and Symptoms – There is little clinical experience with overdosage of Axid in humans. Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal Intravenous median lethal doses in the rat and mouse were 301 mg/kg and 232 mg/kg respectively

Treatment – To obtain up-to-date information about the treatment of overdose, a good resource is your certified regional Poison Control Center Telephone numbers of certified poison control centers are listed in the *Physicians' Desk Reference (PDR)*. In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient.

If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy Renal dialysis for four to six hours increased plasma clearance

PV 2096 AMP [013089]

Additional information is available to the profession on request.

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1. Data on file, Lilly Research Laboratories

[illegible]

The Maryland Pharmacist

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ROBERT THOM

Maryland Pharmacists Association
1989 Membership Directory

THE MARYLAND PHARMACIST

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Commentary

MPhA Membership
A Great Opportunity
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As my year as president winds down, I want to thank each and every one of you for continuing to support the profession through your MPhA membership. Each member is an integral part of the success of our organization.

Over the past six months, membership has steadily increased. Kathy Gauthier and Brain Sanderoff, our Membership Committee Co-chairs, have developed plans to increase our ranks even more. Over the next three months, we will be writing to all non-members inviting them to join with a special offer —15 months of membership for the regular one year's dues. If, as you look over our 1989 Membership Directory, you notice a colleague's name missing let them know *today* about this great opportunity.

Here's our dues structure:

Owner/Manager Members	—	$225*
Employee/Staff Members	—	$115*
Associate Members	—	$100
Hospital Pharmacists	—	$100
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First Year Graduates	—	$ 25
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Joint Membership	—	$200*
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*Includes local association dues.

I want to ask you as a personal favor to take it upon yourself to recruit at least one new member over the next three months. You'd be surprised how receptive pharmacists can be to joining their professional society when a fellow colleague extends an invitation.

Again, thank you for your continued support.

Elwin H. Alpern, P.D.

President

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 27.

Correspondence Course

Salt Substitutes and Salt Replacement Products

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Gossel

Wuest

Goals

The goals of this lesson are to:

1. describe the medical uses for salt replacement and salt substitute products; and
2. discuss the limitations inherent in therapy with these products.

Objectives

At the conclusion of this lesson, pharmacists will be able to:

1. identify the uses for salt replacement and salt substitute products;
2. demonstrate an understanding of the precautions and warnings, adverse effects and toxicities associated with these products;
3. convert metric quantities of sodium into milliequivalents and vice versa;
4. exhibit knowledge on how to reduce dietary sodium intake by nonpharmacologic means; and
5. choose specific points for advising consumers on the correct use of salt replacement and salt substitute products.

Consumers are generally aware of medical recommendations that they reduce their dietary sodium intake since sodium is a well known risk factor in hypertension and vascular disease. Many OTC drug product labels, food labels, and recipes now list sodium values, and some manufacturers highlight the low sodium or salt-free content.

Many consumers are also aware that it is advisable to supplement their normal dietary sodium intake with salt tablets or salt supplement beverages during periods of heavy exercise and sweating in hot climates. While there may appear to be some contradiction in emphasis about the importance of these two extremes of salt intake, there is good reason for both.

There are two groups of OTC products that are of special interest for consumers who wish to follow either recommendation. These are the salt replacement tablets (Table 1) and salt substitutes (Table 2).

This article discusses the role of salt for oral therapy of heat-related illness, and the use of salt substitutes in sodium-restricted dietary programs. It highlights their uses and limitations, benefits and precautions. It also presents important information to convey to consumers interested in these OTC products, or in lowering sodium intake by nonpharmacologic means.

Salt Replacement

Heat-Related Illness. This is a major concern of persons who work or exercise in high temperatures. Such illness is not confined to remote tropical areas, or even to the warm subtropical states within the U.S. Serious medical problems can occur in temperate zones as well.

Table 1

Representative OTC Salt Replacement Products

Product (Mfr)	Dosage Form, Concentration
Sodium Chloride (Purepac)	Tablets, 650 mg
Sodium Chloride (Various)	Tablets, 1 gm
Slo-Salt (Mission)	Tablets, slow release, 600 mg
Sodium Chloride (Lilly)	Tablets, enteric coated, 1 gm
Sodium Chloride (Lannett)	Tablets, 1.07 gm
Sodium Chloride (Lilly)	Tablets, 2.25 gm
Sodium Chloride with Dextrose (Various)	Tablets, 650 mg
Heatrol* (Otis Clapp)	Tablets, 635 mg

*Also contains KCl, 40.6 mg; Calcium phosphate, 31.5 mg, Magnesium carbonate, 9.1 mg.

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Table 2

Representative OTC Salt Substitute Products

Product (Mfr)	Potassium Content mg/5 gm	Potassium Content mEq/5 gm
Adolph's Salt Substitute* (Adolph's)	2448	63
Adolph's Seasoned Salt** (Adolph's)	1328	34
Co-Salt* (USV Pharmaceutical)	2340	60
Diasal* (Fougera)	2340	60
Featherweight "K" Salt* (Chicago Dietetic Supply)	448.5	11.5
Featherweight Seasoned Salt Substitute* (Chicago Dietetic Supply)	409.5	10.5
Morton Salt Substitute* (Morton Salt Co)	2736	70
NoSalt* (Norcliff-Thayer)	2736	70
Neocurtasal* (Winthrop-Breon)	2340	60
Sweet and Low Nu-Salt** (Cumberland)	2640	68

*Sodium content (mg/5 gm): ≤ 0.5

**Sodium content (mg/5 gm): <1

There are three clinical heat-related illness syndromes: heat cramps, heat exhaustion, and heat stroke.

Heat cramps are painful skeletal muscle contractions that result from excessive loss of sodium in sweat and urine. There is brief, often excruciating, cramping in muscles that have undergone extensive exercise. Cramping occurs more commonly in persons who are physically fit and well-acclimatized. They are most common at the end of the day, while walking, relaxing, or taking a cool shower. The painful paroxysms last a few minutes and disappear spontaneously.

Heat exhaustion occurs with continuous fluid and sodium loss. The body temperature increases and the blood pressure drops as a result of extracellular fluid and blood volume contraction. Subjective feelings of weakness and/or lassitude may result from concurrent loss of intracellular potassium.

Heat stroke is the least common, but most serious heat-related illness. It occurs when the body temperature is raised above 105 to 106° F and the brain's heat regulating mechanisms become inactivated. Symptoms include weakness, headache, dizziness, and diminished sweating. If not treated, collapse, coma and death are common.

Heat-related illness results with one or more of the following conditions: (1) severely hot temperature, (2) high humidity, (3) extreme physical exertion, and (4) lack of acclimatization to the environment. Any person who is otherwise physically fit may still experience adverse effects to heat. Individuals at high risk generally have a history of heat intolerance or skin disorders, or are physically unfit and/or overweight.

The primary concern is that extensive fluid and sodium loss occur secondary to excessive sweating, and this is often aggravated by poor electrolyte replacement. Taking salt tablets to minimize dizziness and/or fainting during hot weather is usually safe when properly undertaken. But there are also inherent problems with this therapy. There is, in fact, a current concern that individuals should not undertake salt replacement therapy without medical supervision.

There are two populations that must be acknowledged when considering salt replacement therapy — those who are acclimatized to their environment and those who are not. Each is treated differently.

Acclimatization to heat represents physiological adaptation so that the individual is able to tolerate work and/or exercise in a hot environment. This may require a few days to one or more weeks to occur. With acclimatization, the cardiovascular, endocrine and exocrine systems adapt to the increased temperatures. The extracellular fluid space may expand by 10 percent aided by the action of water conservation and salt-retaining hormones. Acclimatized individuals produce a larger volume of sweat that contains a lower concentration of sodium. The maximal rate of sweat loss for the unacclimatized individual is reported to be 1.5 L/hr, and for the acclimatized person, 2.5 L/hr. Sodium loss is 100 mEq/L and 70 mEq/L respectively. Acclimatized individuals are, therefore, able to maintain better internal control over electrolyte loss and regulation of temperature.

The sodium balance may be affected in two ways. First, sodium is lost by those who sweat excessively but do not replace it during the first few days of active sweating. Second, individuals may become hyponatremic by consuming large quantities of water without concurrent salt replacement.

Supplementation in heat-acclimatized persons who maintain a normal daily dietary salt intake of about 10 gm is reportedly not necessary because they really do not lose that much sodium. Unacclimatized persons may lose 15 to 25 gm sodium/day in hot environments so they are candidates for salt replacement.

Salt replacement can be undertaken safely by increasing salt intake by 5 to 15 gm/day, depending on the severity of heat exposure and sodium loss. Except for the first week or two until the person becomes acclimatized, routine use is not advised. Salt replacement should not be attempted whenever concurrent fluid intake is inhibited.

Unacclimatized persons who exercise in hot climates for brief periods need not be concerned about supplementation. Mild sodium losses will be balanced by gains achieved from a normal diet. Persons who are exposed to prolonged physical exertion in hot temperatures may be candidates for sodium replacement therapy, but each person will have a different requirement. Whenever there

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is any question about the possible necessity for salt replacement, the individual should consult a physician.

Safety. Oral salt replacement products may cause gastric irritation with nausea and/or vomiting, weakness, increased potassium loss, and prickly heat and skin eruptions. Acclimatization may be delayed. Replacement therapy can also induce severe edema, hypertensive crisis, and neurological deterioration with acute psychosis.

Can Any Liquid Be Used to Replenish Fluid and Electrolyte Losses?

Table 3 lists the sodium, potassium and carbohydrate content of common liquids. Milk is rich in sodium, potassium and carbohydrate (which provides energy). It is not tangy and, thus, is a poor thirst quencher. Milk also contains protein and fat which are difficult to digest during exercise, and protein also increases the body temperature.

Orange juice is an excellent source of sodium, potassium, and carbohydrate, and is a good thirst quencher. Its acidity may upset the stomach during periods of stressful exercise such as competitive sports.

Colas, ginger ale, and beer provide carbohydrate and are good thirst quenchers. However, they do not supply needed electrolytes.

Coffee and tea provide neither electrolytes nor carbohydrate in the unsweetened state. Further, caffeine-containing beverages are central nervous system stimulants and can increase sweating and additional fluid loss.

Commercial mixtures of electrolytes such as Gatorade® are excellent thirst quenchers and can quickly replenish lost electrolytes. They are generally classed as food, rather than drug items. Consequently, FDA does not allow medical claims to be made for them.

Salt Substitutes

The average adult requires 1.2 to 3.3 gm of sodium each day. It is estimated that most people actually consume 2.3 to 6.9 gm of sodium daily, or twice the quantity needed. Sodium is abundant in the food supply; nearly all foods contain it. Discretionary salting, that is , the addition of salt during cooking or at the table, accounts for less than 30 percent of intake.

Salt substitute products are used primarily by persons with cardiovascular disease. Hypertension alone occurs in nearly 60 million Americans. It is the leading contender for causing stroke, and a major contributor to heart and kidney failure, and heart attack in the U.S.

Diuretics are frequently prescribed to treat hypertension. Increased potassium excretion possibly leading to hypokalemia may be one outcome of diuretic therapy. However, potassium chloride supplementation poses significant compliance problems due to its unpalatability and/or high cost. Physicians may, therefore, recommend that persons regularly use a salt substitute product in place of prescribed potassium therapy. Such supplementation is an acceptable means for providing potassium to maintain normal serum levels.

Table 3

Sodium-Potassium-Carbohydrate Comparison of Some Commonly Used Food Liquids

Food Liquid	Sodium mEq/L	Potassium mEq/L	Carbohydrate gm/8 oz
Whole milk	22	37	12.5
Orange juice	< 1	43	27
Cola	6	< 1	27.6
Ginger Ale	3	1	20
Beer	1	4.7	10.6 (CHO) 8.9 (ALC)
Coffee (plain)	1	1	1
Tea (plain)	1	1	< 1

Modified from: Balakian G: What are the "ades" all about? *Medical Times* 99(9):202, 1971

Individuals report significantly differing taste preference for the various salt substitute products. This objective preference is undoubtedly influenced by the quantity of product used, the type of food to which it is added, and other personal factors. Pharmacists can stock several different brands and suggest that their customers first purchase small-size containers to determine which taste they like best, before they purchase in quantity.

Safety. Persons who have normal renal function, and others with renal failure that does not involve urine loss, rarely develop hyperkalemia from using salt substitute products. In persons with renal pathology, the diseased kidney may already be functioning maximally as far as potassium excretion. Persons on sodium-restricted diets or persons taking potassium-retaining drugs would be at higher risk if using a salt substitute. Products that contain more than 975 mg (25 mEq) potassium in a daily dose should not be used by persons with renal disease.

Products purported to be "light-salt" are not equivalent to salt substitute products. One such product, Lite-Salt®, is an iodized mixture of sodium and potassium chlorides. It contains approximately 130 mEq sodium and 37 mEq potassium per teaspoonful. Cardiovascular patients on low sodium diets who use these products may experience toxicity.

New FDA Regulations for Labeling of Food Items

There are now federal regulations that mandate the labeling of food products for sodium content. New food products introduced onto the marketplace must indicate sodium content per serving on the label. Many manufacturers of older products have changed their labeling to meet these requirements. Specific descriptive phraseology that is used on the labels is stated as follows: **Sodium free** foods contain less than 5 mg/serving; **very low sodium** foods contain up to 35 mg/serving, and **low sodium** foods have been formulated to contain less than 25 percent of the sodium content as the processed or high-sodium nonprocessed foods they are promoted to replace. The label must show comparisons of the sodium content per serving with that of the food it replaces.

Table 4

Salt and Sodium Conversions

• Grams to milligrams	Multiply weight in grams by 1,000
• Sodium into salt (NaCl) equivalent	Milligrams of sodium content ÷ 0.40 = milligrams of salt
• Salt into sodium	Milligrams of salt × 0.40 = milligrams of sodium
• Sodium in milligrams to sodium in milliequivalents	Milligrams of sodium ÷ 23
• Milliequivalents of sodium to milligrams of sodium	Milliequivalents of sodium × 23 = milligrams of sodium
• Millimoles to milliequivalents	1 for 1 (i.e., 100 mmol of sodium = 100 milliequivalents)

Drug Interactions Involving Sodium and Potassium

Potassium-sparing diuretics (i.e., amiloride-Midamor®, spironolactone-Aldactone®, triamterene-Dyrenium®) decrease potassium excretion. The additional intake of potassium in salt substitute products could lead to fatal hyperkalemia. The manufacturers of potassium-sparing diuretics, as well as those of prescription potassium supplements, contraindicate against concurrent use with salt substitutes.

While these two types of agents are used to combat hypokalemia, such therapy must be undertaken in a hospital with the patient under close supervision. Persons should not initiate salt substitute therapy if they are taking a potassium-sparing diuretic without first checking with their physician.

The potassium-sparing/sodium-depleting diuretic products (i.e., Aldactazide®, Dyazide®, Maxzide® and Moduretic®) are borderline as far as being contraindicated for use along with salt substitutes. Patients taking them should also check with their physician before using OTC salt substitutes.

The **angiotensin converting enzyme (ACE) inhibitors** (i.e., captopril-Capoten®, enalapril-Vasotec®, lisinopril-Prinivil® and Zestril®) also cause potassium retention. The mechanism for retention differs from that of the potassium-sparing diuretics, but the end result, hyperkalemia, can be the same.

ACE inhibitors decrease the production of aldosterone by the adrenal gland. This mineralocorticoid conserves sodium at the expense of potassium in the distal renal tubule. By decreasing its secretion, ACE inhibitors reduce this exchange, and increase potassium retention. Patients taking ACE inhibitors should consult with their physician before using OTC salt substitutes.

Both salt substitutes and salt replacement products can interact with **lithium**. Lithium is in the same group of elements as sodium and potassium (i.e., monovalent cations). These three ions compete with each other for the transport system that carries them across cellular membranes.

In the kidney, potassium and sodium can affect lithium excretion/retention. There is little information on a significant problem with potassium, but increased sodium intake may result in enhanced excretion of lithium with lessened therapeutic effect. Decreased sodium intake can increase both the pharmacologic and toxicologic effects of lithium salts.

Lithium has a narrow therapeutic index. Patients taking it should maintain a constant intake of sodium to avoid fluctuations in lithium levels.

Counseling Consumers

Consumers who desire to replace sodium during periods of active exercise in hot climates should be dissuaded from ingesting salt poured in their hand or added to beverages directly from the shaker. Such ingestion of unmeasured quantities may result in salt-induced toxicity. Commercially available salt tablets contain measured quantities and are labeled with specific directions for use.

Consumers should be advised not to use salt replacement products if they are on a low sodium diet, or if they have cardiovascular or kidney disease without first checking with a physician. They should also not take the products alone, without drinking at least a full glass of water.

As stated earlier, many processed foods have a high sodium content. Individuals on a low sodium diet may not realize that the salt they add to food during cooking or at the table represents less than one-third of their total daily intake. In fact, bread supplies up to half of the daily sodium intake of many people. Certain medications also may contain significant sodium.

The use of salt substitutes alone, therefore, without concurrently modifying the diet by using low-sodium foods and avoiding OTC medications rich in it, may not reduce sodium intake sufficiently. Consumers should be instructed to carefully study food and OTC medication labels for listed sodium content, and to use these data in calculating their total daily salt intake.

Some food and drug product labels state their sodium content in grams or milligrams, and others express it in milliequivalents. Pharmacists may instruct consumers on how to convert milligrams to milliequivalents, and vice versa, so they can calculate the amount of sodium they ingest each day. The conversion information is presented in Table 4.

Consumers should avoid alcohol during periods of high temperatures because it increases the metabolic rate, induces dehydration, and decreases sound judgement. They should limit intake of drugs with anticholinergic action during these periods since they reduce the ability to sweat and, thus, hinder the body's heat exchange system.

There are many cookbooks that contain salt-free recipes. The American Heart Association also provides recipes for salt-free, flavored dishes. Pharmacists can supply these books and recipes, and even serve as a repository for low-sodium recipes from their own patients, who wish to share them with others.

Dickinson's Pharmacy

Jim Dickinson

How about a li'l aardvark? One of my favorite publications is the *Federal Register,* that hefty, irregular daily wad of federal government rulemakings and notices. It will come singly, and not at all, and then three or four all at once.

Whenever it does come, it's a comforting reminder of the inefficiency of government. I never forget something one of my mentors once said—"The greatest threat to individual freedom would be if our government ever became efficient!"

On January 23, 1989, our government published a proposal in the *Federal Register* to encourage more kickbacks from providers to Medicaid and Medicare agencies (a truly *efficient* government would have just done it, without warning).

Specifically, the Department of Health and Human Services' Office of the Inspector-General, which has been inefficiently trying for years to eliminate fraud and abuse, wants to lay down "safe harbor" rules for acceptable kickbacks paid by providers.

Here's how one such example worked in a pharmacy context, recently. Officially termed a "rebate," this amounted to an upfront offer of $900,000 off a large mail-order drug company's bid price to the California Public Employees Retirement System. Since the mail-order company's bid price was $1.1 million, the "rebate"—which it said could be financed from savings on the acquisition of generic drugs—amounted to an 82% discount off what should already have been the company's best effort and lowest bid.

Two other final bidders at that time each had offered prices that were within the same $1.1 million ballpark, but they could hardly afford to go in that low. Dean Smart, the manager of the PERS program in question, told me he believed the contract was awarded *because* of the $900,000—"It's pretty hard to argue with that much money!"

It may be a matter of semantics, but my idea of a legitimate "rebate" is a percentage of savings actually achieved, *after* they have in fact been achieved. I think a kickback is an inducement, almost a bribe, to do business, usually paid upfront. I have asked the U.S. Justice Department to give its opinion, but in the meantime, just to be safe—some lawyers can be pretty "antsy"—I won't use either term—I'll use "aardvark" instead (aardvarks eat ants).

The point for pharmacy in all this is that if rules to prevent such aardvarks are not quickly drawn up, we will have managed-care prescription business going automatically to the provider with the deepest pocket.

Indeed, just after I learned about the California contract, I went to a financial analysts meeting in New York at which the same mail order company made a vivid audio-visual presentation—promising to service any contract at 70% lower than the other lowest prices out there.

So confident about this was the presenter that he predicted that within five years, his firm will have the prescription business of one in every three eligible, covered beneficiaries over the age 55—and that company is already dispensing 16 million prescriptions annually.

As I heard all this, visions of aardvarks danced in my head. That helped me remember about Angelo Commito, a figure in organized crime who was recently indicted on racketeering charges in California, involving health benefit programs, unions, prescription drugs and aardvarks.

Patients don't always know about all these things, when they think about prescriptions. When they find out, they tend not to be pleased. In California, a militant group of PERS retirees in Humboldt county was formed specifically to get rid of the mail-order program that was brought to them by an aardvark they didn't know about.

It's the first patient activist group for such a purpose that I've heard of. A few weeks later, I learned of another, similar group in Richmond, Virginia, that's trying to throw out another mail-order drug program that began at the same time as the California plan began—January 1.

Both groups are worried about safety, and both were more than a little interested in a 20-minute, two-part "CBS This Morning" television report on mail-order drugs that aired on February 8 and 9. It was hardly a flattering portrayal of the mail-order industry.

If you would like to see such a patient's group in your area, I would be more than happy to help them get started. Have the organizer write me at P.O. Box 848, Morgantown, WV 26507-0848.

And then there's this *Federal Register* proposal on aardvarks. If you would like to tell our inefficient government what it should do about prescription drug aardvarks, send your comments to the Office of the Inspector General, Department of Health and Human Services, Attention LRR-17-P, Room 5246, 330 Independence Avenue, S.W., Washington, D.C. 20201.

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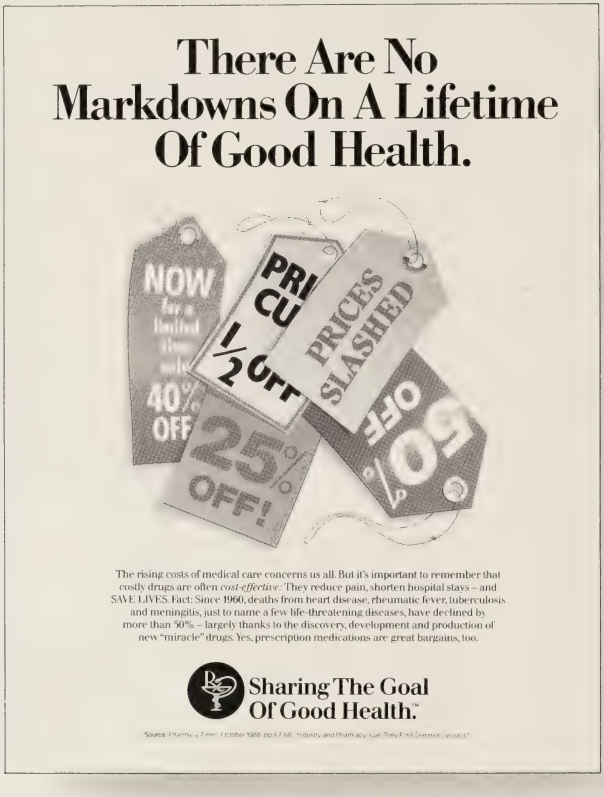

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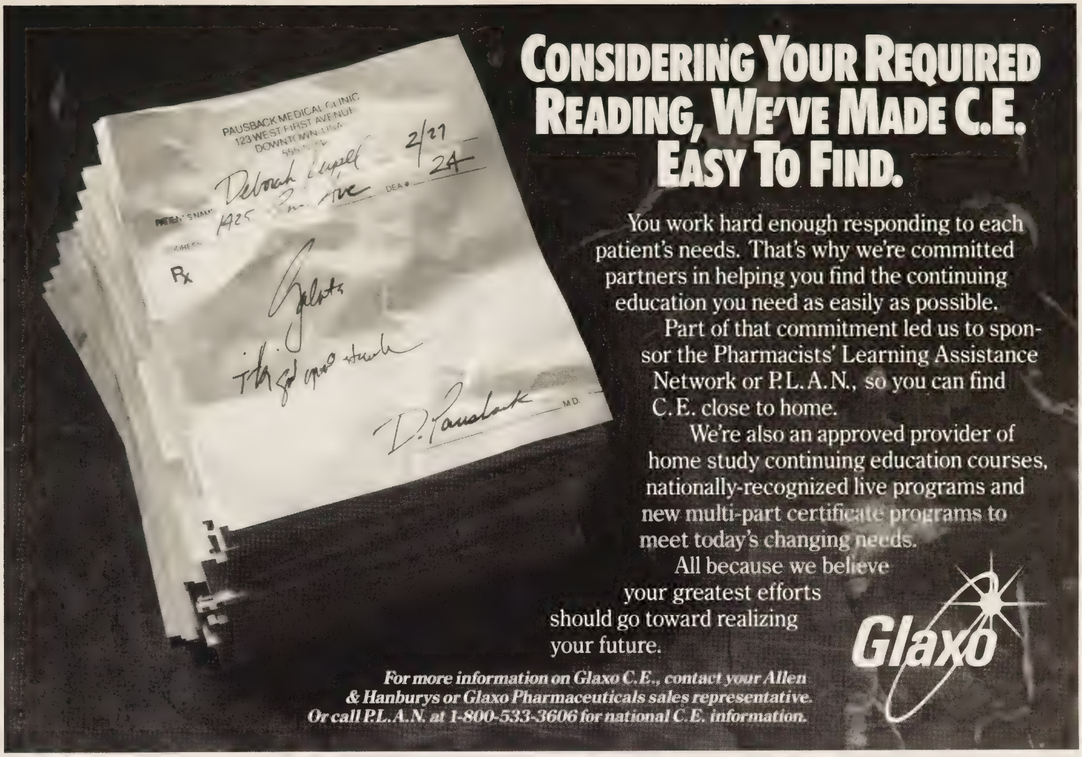

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Shelton, Wesley N.
Sherman, Howard
Sherwood, Jr., Winn
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Silverman, Irvin I.
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nizatidine

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- 93% reported not missing any doses

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nizatidine capsules
300 mg
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Convenience Pak
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nizatidine capsules
150 mg

Convenience Pak is available at no extra cost

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Indianapolis, Indiana
46285

AXID®

nizatidine capsules

Brief Summary

Consult the package literature for complete information.

Indications and Usage: Axid is indicated for up to eight weeks for the treatment of active duodenal ulcer In most patients, the ulcer will heal within four weeks

Axid is indicated for maintenance therapy for duodenal ulcer patients at a reduced dosage of 150 mg h s. after healing of an active duodenal ulcer. The consequences of continuous therapy with Axid for longer than one year are not known

Contraindication: Axid is contraindicated in patients with known hypersensitivity to the drug and should be used with caution in patients with hypersensitivity to other H_2-receptor antagonists

Precautions: *General* – 1 Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy

2 Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done Part of the dose of nizatidine is metabolized in the liver In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects

Laboratory Tests – False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine

Drug Interactions – No interactions have been observed between Axid and theophylline, chlordiazepoxide, lorazepam, lidocaine, phenytoin, and warfarin Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system, therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b i d., was administered concurrently

Carcinogenesis, Mutagenesis, Impairment of Fertility – A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice, although hyperplastic nodules of the liver were increased in the high-dose males as compared with placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high-dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement as compared with concurrent controls and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery are not considered evidence of a carcinogenic potential for Axid

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, mouse lymphoma assay, chromosome aberration tests, and a micronucleus test.

In a two-generation, perinatal and postnatal fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny

Pregnancy – Teratogenic Effects – Pregnancy Category C – Oral reproduction studies in rats at doses up to 300 times the human dose and in Dutch Belted rabbits at doses up to 55 times the human dose revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

Nursing Mothers – Studies conducted in lactating women have shown that <0.1% of the administered oral dose of nizatidine is secreted in human milk in proportion to plasma concentrations. Caution should be exercised when administering nizatidine to a nursing mother.

Pediatric Use – Safety and effectiveness in children have not been established

Use in Elderly Patients – Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among reported adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs < 0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to determine whether these were caused by nizatidine

Hepatic – Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients and was possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L) and, in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular – In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects

CNS – Rare cases of reversible mental confusion have been reported

Endocrine – Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to Axid Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred

Hematologic – Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H_2-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported

Integumental – Sweating and urticaria were reported significantly more frequently in nizatidine- than in placebo-treated patients. Rash and exfoliative dermatitis were also reported

Hypersensitivity – As with other H_2-receptor antagonists, rare cases of anaphylaxis following administration of nizatidine have been reported. Because cross-sensitivity in this class of compounds has been observed, H_2-receptor antagonists should not be administered to individuals with a history of previous hypersensitivity to these agents. Rare episodes of hypersensitivity reactions (eg, bronchospasm, laryngeal edema, rash, and eosinophilia) have been reported

Other – Hyperuricemia unassociated with gout or nephrolithiasis was reported Eosinophilia, fever, and nausea related to nizatidine administration have been reported.

Overdosage: Overdoses of Axid have been reported rarely. The following is provided to serve as a guide should such an overdose be encountered

Signs and Symptoms – There is little clinical experience with overdosage of Axid in humans. Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous median lethal doses in the rat and mouse were 301 mg/kg and 232 mg/kg respectively

Treatment – To obtain up-to-date information about the treatment of overdose, a good resource is your certified regional Poison Control Center. Telephone numbers of certified poison control centers are listed in the *Physicians' Desk Reference (PDR)*. In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient

If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance

PV 2096 AMP [013089]

Additional information available to the profession on request.

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1. Data on file, Lilly Research Laboratories

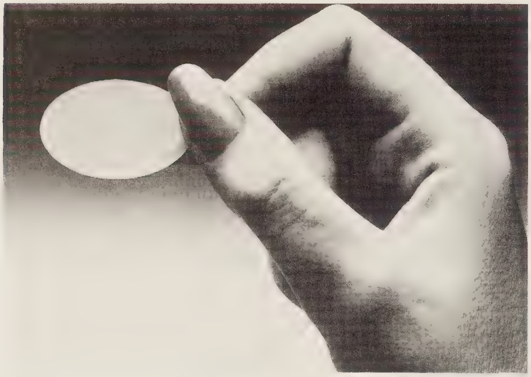
[illegible]

METOCLOPRAMIDE
Syrup
5mg per 5ml
Roxane

Roxane has just introduced Metoclopramide Syrup 5mg/5ml. Packaging includes a 500ml bottle and unit dose patient cups. Roxane's metoclopramide syrup is sugar-free, sodium-free and alcohol free.

Achromycin
Ophthalmic

Storz Ophthalmics, Inc. is now marketing Achromycin ophthalmic products including a 1% ophthalmic suspension and ointment. The broad spectrum of Achromycin includes *Chlamydia trachomatis* and *Neisseria gonorrhoeae.*



Minitran Transdermal Nitroglycerin is a new transparent patch from 3M Riker for use in treating angina. The Minitran patch generally costs less than other leading patches according to the 1988 AWP Redbook.

Thanks to financial support from SAMPA and BMPA, the MPhA headquarters now has new window blinds and draperies. Thanks to an article in the *Baltimore Sun Magazine* the B. Olive Cole Museum, housed at headquarters, has had more than 90 visitors in the past month.

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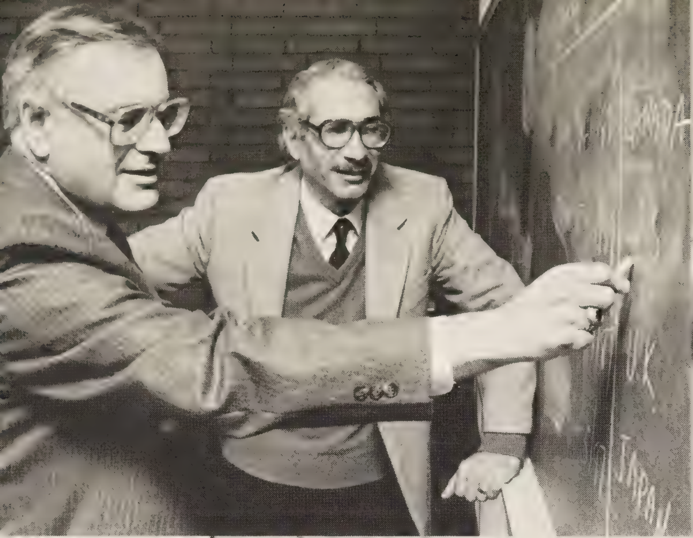
June 1988—Annual Convention Coverage
July 1989—Legislative Wrap-Up
August 1989—Third-Party Issue



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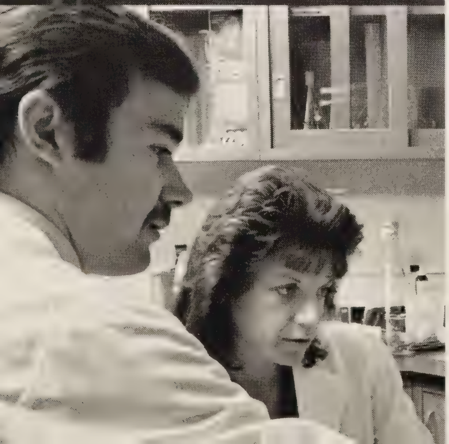

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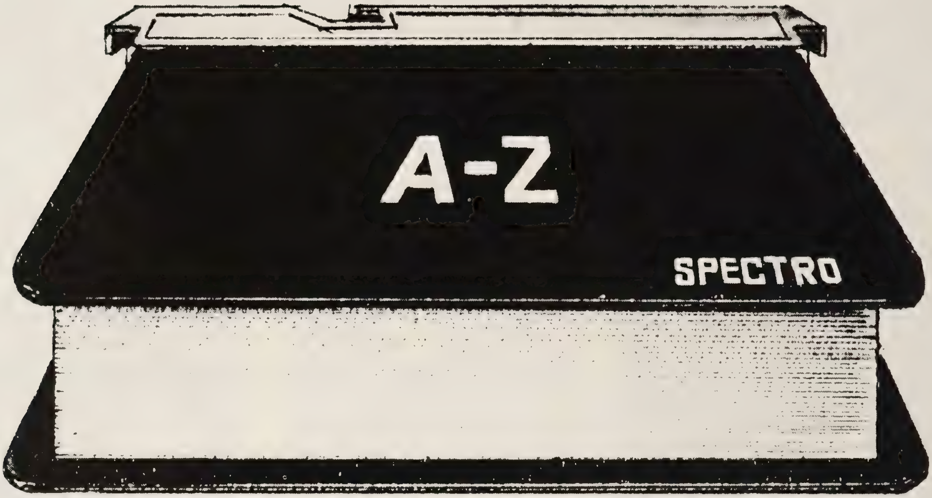

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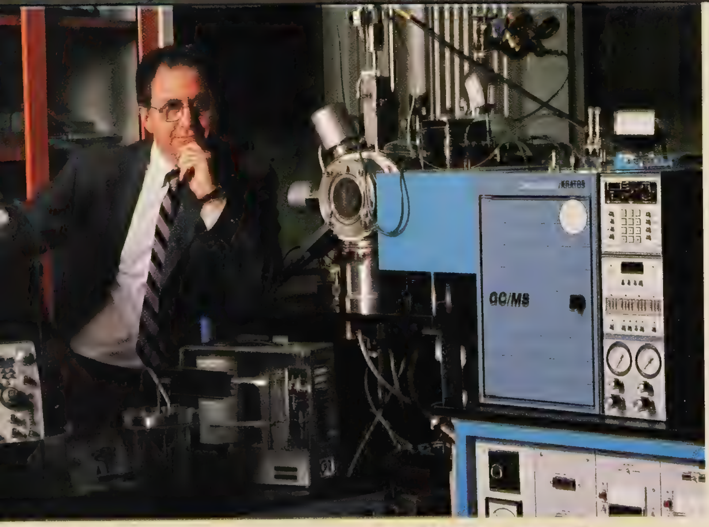

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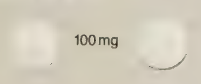
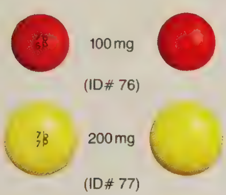

100 mg

(ID# 0037)

ORPHENADRINE CITRATE SR TABLETS

Compare to Choledyl


100 mg

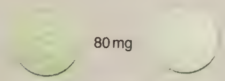
(ID# 76)

200 mg

(ID# 77)

OXTRIPHYLLINE ENTERIC COATED TABLETS

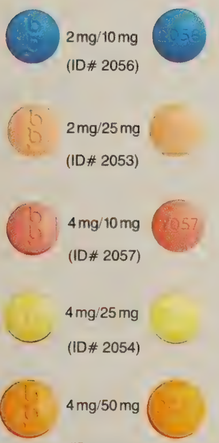
Compare to Peritrate SA


80 mg

(ID# 0017)

PENTAERYTHRITOL TETRANITRATE SR TABLETS

Compare to Triavil


2 mg/10 mg

(ID# 2056)

2 mg/25 mg

(ID# 2053)

4 mg/10 mg

(ID# 2057)

4 mg/25 mg

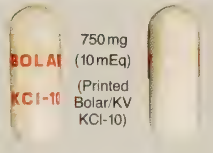
(ID# 2054)

4 mg/50 mg

(ID# 2055)

PERPHENAZINE/AMITRIPTYLINE HCl TABLETS

Compare to Micro-K 10 Extencaps



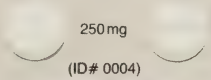
750 mg

(10 mEq)

(Printed Bolar/KV KCl-10)

POTASSIUM CHLORIDE CR CAPSULES

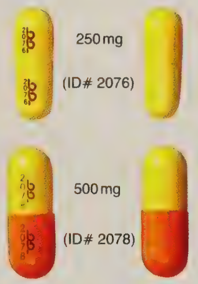
Compare to Mysoline


250 mg

(ID# 0004)

PRIMIDONE TABLETS

Compare to Pronestyl


250 mg

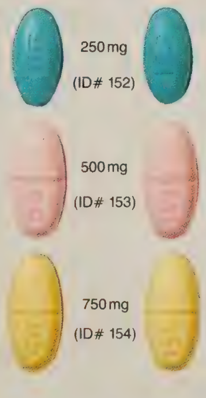
(ID# 2076)

500 mg

(ID# 2078)

PROCAINAMIDE HCl CAPSULES

Compare to Procan SR


250 mg

(ID# 152)

500 mg

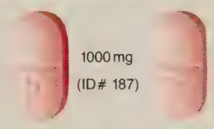
(ID# 153)

750 mg

(ID# 154)

PROCAINAMIDE HCl SR TABLETS

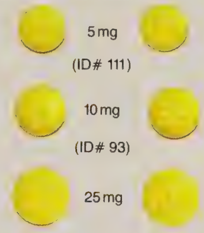
Compare to Procan SR


1000 mg

(ID# 187)

PROCAINAMIDE HCl SR TABLETS

Compare to Compazine


5 mg

(ID# 111)

10 mg

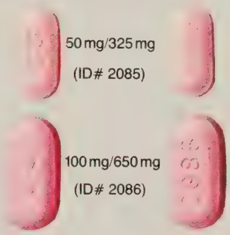
(ID# 93)

25 mg

(ID# 112)

PROCHLORPERAZINE MALEATE TABLETS

Compare to Darvocet-N


50 mg/325 mg

(ID# 2085)

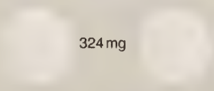
100 mg/650 mg

(ID# 2086)

PROPOXYPHENE NAPSYLATE and ACETAMINOPHEN TABLETS

*C IV (Controlled Drug Class IV)

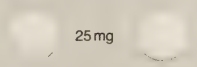
Compare to Quinaglute Dura Tabs


324 mg

(ID# 3000)

QUINIDINE GLUCONATE SR TABLETS

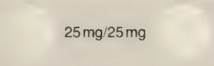
Compare to Aldactone


25 mg

(ID# 5000)

SPIRONOLACTONE TABLETS

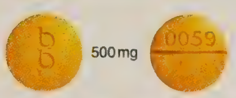
Compare to Aldactazide


25 mg/25 mg

(ID# 0129)

SPIRONOLACTONE and HYDROCHLOROTHIAZIDE TABLETS

Compare to Azulfidine

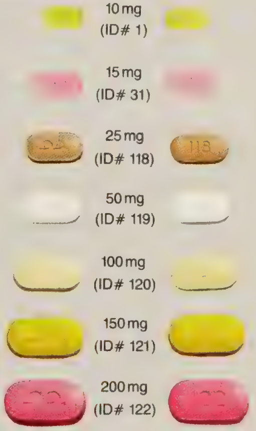


500 mg

(ID# 0059)

SULFASALAZINE TABLETS

Compare to Mellaril


10 mg

(ID# 1)

15 mg

(ID# 31)

25 mg

(ID# 118)

50 mg

(ID# 119)

100 mg

(ID# 120)

150 mg

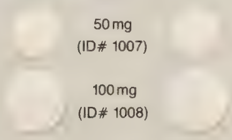
(ID# 121)

200 mg

(ID# 122)

THIORIDAZINE HCl TABLETS

Compare to Desyrel


50 mg

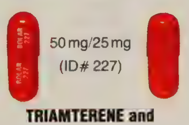
(ID# 1007)

100 mg

(ID# 1008)

TRAZODONE HCl TABLETS

Compare to Dyazide



50 mg/25 mg

(ID# 227)

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Continuing Education Quiz

The Maryland Pharmacist **MAY 1989**

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by August 1, 1989. A continuing education certificate for one contact credit) will be mailed to you within 30 days. Please type or print clearly.

Name ______________________________

Social Security Number ______________________________

Address ______________________________

City/State/Zip ______________________________

Is this program used to meet your mandatory CE? [ ] Yes [ ] No

Did this article achieve its stated objectives? [ ] Yes [ ] No

How long did it take you to complete the program? __________ minutes

Salt Substitutes and Replacement Products

1. The primary concern in heat-related disorders is the loss, through sweating, of which of the following ions?
   a. Chloride
   b. Magnesium
   c. Calcium
   d. Sodium

2. When reading the labels of food products with their sodium content expressed as milliequivalents, the equivalent amount of milligrams of sodium can be calculated by:
   a. dividing the milliequivalents of sodium by 23.
   b. multiplying the milliequivalents of sodium by 23.
   c. dividing the milliequivalents of sodium by 40.
   d. multiplying the milliequivalents of sodium by 40.

3. Which of the following drugs is LEAST likely to cause hyperkalemia in a patient using a salt substitute?
   a. Aldactone®
   b. Capoten®
   c. Lithobid®
   d. Vasotec®

4. In acclimatized persons, the extracellular fluid space:
   a. decreases.
   b. expands.

5. Oral salt replacement products are LEAST likely to cause:
   a. gastric irritation.
   b. increased potassium retention.
   c. weakness.
   d. prickly heat.

6. Which of the following is most likely to decrease the therapeutic effect to lithium salts when taken concurrently?
   a. Salt replacement products
   b. Salt substitute products

7. Of the following, the salt substitute that contains the largest amount of potassium per 5 gm serving is:
   a. Adolphs®.
   b. Diasal®.
   c. Featherweight®.
   d. NoSalt®.

8. Individuals who are LEAST likely to succumb to heat-related illness are those:
   a. who are overweight.
   b. who are physically unfit.
   c. who are acclimatized.
   d. with a history of skin disorders.

9. Using the conversion chart in Table 4, it can be determined that products containing 200 mg of salt (sodium chloride) contain:
   a. 8 mg of sodium.
   b. 16 mg of sodium.
   c. 80 mg of sodium.
   d. 160 mg of sodium.

10. ACE inhibitors interact with salt substitute products because there is a potential for increased potassium retention due to the ACE inhibitor's action on:
    a. adrenocorticotropic stimulating hormone.
    b. aldosterone.
    c. antidiuretic hormone.
    d. intrinsic factor.

AN INVITATION

As President of MPhA this year as well as the Convention Chairman, it has been a great challenge to improve the Annual Convention. I think we've succeeded!

This year, convention attendees can earn 13.5 CE credits, nearly twice as many as in the past. Our business meeting has been reduced to one day to allow more time for education. In addition, we have redesigned our Trade Exposition to include luncheon with our exhibitors.

As for social events, along with the fun and feast of the Annual Crab and Chicken Feast we've included a 50's Sock Hop and Party so be sure to bring your saddle shoes and poodle skirts along for a great time.

Because I believe that the convention should be convenient to all, we have selected Monday, June 20 to be a perfect day for those who can only attend for one day. Why not come down on Sunday, enjoy a day at the beach and then earn 6 hours of CE on Monday?

I encourage every pharmacist in Maryland to attend the 107th Annual MPhA Convention. See you in OC!

Elwin Alpern, P.D.
MPhA President

PROGRAM

Sunday, June 18, 1989

12:00 - 5:00 pm	Registration Opens
2:00 - 5:00 pm	Wine and Cheese Reception
9:00 - 11:00 pm	Welcoming Cocktail Party

Monday, June 19, 1989

7:30 - 8:30 am	Continental Breakfast
8:30 - 12:30 pm	Continuing Education Seminar *Changing Faces in Long Term Care —Some New Wrinkles* Part I
10:00 - 12:00 am	SAMPA Brunch and Fashion Show
12:30 - 2:30 pm	Trade Exposition and Luncheon
2:30 - 4:30 pm	Continuing Education Seminar *Medic Alert: Pharmacists Helping the Public*
6:30 pm	Crab and Chicken Feast Old Time Square Dance Hoe Down Berlin Fire Hall

Tuesday, June 20, 1989

7:30 - 8:30 am	Continental Breakfast
8:30 - 12:30 pm	Continuing Education Seminar *Changing Faces in Long Term Care —Some New Wrinkles* Part II
10:00 - 12:00 am	SAMPA Breakfast and Seminar *Living with Arthritis*
12:30 - 2:30 pm	Trade Exposition and Luncheon
2:30 - 3:30 pm	Continuing Education Seminar *Extrinsic Asthma: The Role of the Pharmacist*
9:00 - 11:30 pm	Sock Hop and '50s Party

REGISTRATION

To register for the 107th Annual Convention of the Maryland Pharmacists Association, complete the registration form on the top portion of the back page of this brochure. Please print or type clearly. Return the form, with your check or money order for the total convention registration to the MPhA Offices.

Admission to all functions will be by ticket or badge. Pick up badges and other registration materials at the MPhA Registration Desk beginning Sunday, June 19 at 12:00 noon or on Monday, June 20 at 8:30 am. You must register with the MPhA to utilize special convention hotel rates. Spouses must register or purchase function tickets to attend any special functions.

Full MPhA or Spouse/Guest Registration includes all meetings and social events. Single Day registration includes all meetings and social events for that day only. Single Day registrants should indicate which day they plan to attend.

Registration Fees	*Before June 10*	*After June 10*
MPhA Member	$ 85.00	$ 95.00
Spouse/Guest	$ 75.00	$ 85.00
Non-member	$135.00	$145.00
Pharmacy Student	no charge	no charge
Children Under 18	no charge	no charge
Single Day	$ 40.00	$ 50.00
Crab and Chicken Feast		
Children Under 12	$ 8.50	$ 13.50
Extra Adult/Students	$ 17.50	$ 22.50
MPhA Annual Banquet		
Children Under 12	$ 17.00	$ 22.00
Extra Adult/Students	$ 22.00	$ 27.00
SAMPA Brunch	$ 10.00	$ 10.00
SAMPA Seminar	$ 10.00	$ 10.00

Wednesday, June 21, 1989

7:30 - 8:30 am	Continental Breakfast
8:30 - 12:30 pm	MPhA House of Delegates Business Session
6:00 - 7:00 pm	Cocktail Reception
7:00 - 9:00 pm	MPhA Annual Awards and Installation Banquet

Thursday, June 22, 1989

9:00 - 12:30 pm	Simon Solomon Seminar *Diabetes Management— A Hands-on Approach*

CONTINUING EDUCATION

Changing Faces in Long Term Care—
Some New Wrinkles

Part I
Monday, June 19, 8:30 am–12:30 pm
Part II
Tuesday, June 20 8:30 am–12:30 pm

This two-part seminar will update pharmacists on the latest clinical, legislative, regulatory, and financial issues affecting long term care pharmacy. Focusing on ambulatory as well as institutional care of the elderly, this program will have information for all pharmacists.

Seminar speakers will include:

Deborah Wertheimer, M.D., a physician specializing in gerontology.
Beverly Baldwin, Ph.D., an expert on caregiver stress.
Janice MacGregor, Director of the Maryland Office on Aging Senior Outreach Program.
Peter Lamy, Ph.D., 1988 Remington Medalist, and Director of the UMAB Elder Care Program.

The Pharmacist and Medic Alert

Monday, June 19, 2:30–4:30 pm

Increasing public awareness of the Medic Alert system is the theme for this program. Speakers will be addressing the need for active pharmacist involvement in promoting this life-saving system

Extrinsic Asthma: The Role of the Pharmacist

Tuesday, June 20, 2:30–3:30 pm

Learn about how to help patients with extrinsic asthma through unique multi-media presentation. A video-tape with case examples will be followed by a question and answer session with an expert in pulmonary therapy. Pick up a self-study booklet to help earn even more continuing education credits.

Diabetes Management—A Hands On Approach
The Simon Solomon Lecture

Thursday, June 22, 9:00 am–12:30 pm

Looking at the role of pharmacists in diabetes care, this program will show how to assist diabetics in maintaining control of their disease, understanding the unique needs of the diabetic, and how to establish a diabetic care center in a community pharmacy.

Seminar speakers include:

Belinda Tilley, Pharm.D., clinical pharmacy coordinator at GBMC Hospital.
Carey Hillman, Ames Diagnostic Division representative.
and
A representive from the American Diabetes Association.

The Maryland Pharmacy Continuing Education Coordinating Council is approved by the American Council on Pharmaceutical Education as a provider of continuing education for pharmacists. The 107th Annual MPhA Convention enables an attendee to earn 13.5 contact hours (1.35 CEUs) of approved CE credit.

TRADE EXPOSITION

Keep up with the latest, most exciting developments and the newest products on the market at the MPhA Trade Exposition. Visit every exhibitor and be eligible to win a television!

Join us for lunch in the Exhibit Hall on Monday, June 19 and Tuesday, June 20 from 12:30 to 2:30 p.m.

1988 Exhibitors

Ayerst Laboratories
Bergen Brunswig Corporation
Boehringer Ingelheim
Bristol Laboratories
Burroughs-Wellcome Company
Ciba-Geigy Pharmaceuticals
District Photo, Inc.
Dista
The Drug House, Inc.
Food Plus
E. Fougera & Company
Geneva Generics, Inc.
Glaxo, Inc.
General Computer Corporation
Goldline Laboratories
Health Business Systems, Inc.
Hoechst-Roussel Pharmaceuticals
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Lederle Laboratories
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MAI Basic Four
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E.R. Squibb & Sons, Inc.
USP Convention, Inc.
The Upjohn Company
3 PM, Inc./McKesson
Winthrop Laboratories
Wyeth Laboratories

ACCOMMODATIONS

Once again, the Maryland Pharmacists Association has been able to obtain for attendees discounted rates for one of Ocean City's finest resort hotels. In previous years, the hotel sold out of reserved rooms at the special MPhA convention rate. Don't be disappointed! Mail your reservation form *directly* to the hotel.

All room reservations must be received by the Sheraton **no later than Monday, May 15, 1989**. Otherwise, the Sheraton will be unable to guarantee space availability at these special rates.

Children under 17 stay free of charge *in same room* as parents. Rates are subject to 8 percent room tax. One night deposit is required. Full refund on 72 hours notice to hotel. Rooms are available for check-in at 3:00 p.m. The Sheraton Fontainebleu accepts personal checks *for deposit only.* No personal checks will be accepted after arrival. Credit cards are not accepted for advance deposit. A 72-hour cancellation or change notice is required.

Room Rates

Guest Rooms (per night)			
Single/Double	$115	Cabana Suites	$230
Triple	$129	Studio Suites	$170
Quad	$143		
Condominiums (per week)			
With Maid Service	$900	Without Maid Service	$700

REGISTRATION FORM

Name ________________________

Pharmacy/Company Name ________________________

Mailing Address ________________________

City ____________ State ________ Zip Code ________

Nickname for Badge ____________ Phone ____________

Spouse/Guest Name ________________________

Registration
(indicate number)

_____ MPhA Member
_____ Spouse/Guest
_____ Non-Member
_____ Pharmacy Student
_____ Children Under 18
_____ Single Day

Special Functions
(indicate number)

Crab & Chicken Feast

_____ Children Under 12
_____ Extra Adult/Students

MPhA Annual Banquet

_____ Children Under 12
_____ Extra Adult/Students

Return top portion to MPhA, 650 West Lombard Street, Baltimore, MD 21201

RESERVATION REQUEST

Name ________________________

Mailing Address ________________________

City ____________ State ________ Zip Code ________

Arrival Date ____________ Departure Date ____________

Number in Party (Adults) ____________ (Children) ____________

Indicate which type of accommodation you prefer: ☐ Guest Room ☐ Studio ☐ Cabana ☐ Condo

Mail the bottom portion of this form with one night's deposit to:

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Classified

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

EVERY SUNDAY MORNING at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the pharmacy public relations program, "Your Best Neighbor," the oldest continuous public service show in Baltimore.

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PHARMACISTS REHABILITATION COMMITTEE HOTLINE is (301) 727-0746.

FDA HOTLINE FOR AIDS information is 800-432-AIDS.

ATTENTION—HIRING! Government jobs—your area. Many immediate openings without waiting list or test. $17,840–$69,485. Call 1-602-838-8885. Extension 9494.

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WANTED Futuro flannel lined incontinence pants, size medium. Call Professional Pharmacy (301) 655-2060.

PART TIME PHARMACIST to be utilized when regular pharmacist is on vacation and unexpected periods of illness. No weekends or holidays designated by the State of Maryland. Position is located at a State hospital. If interested, contact Emanuel G. Freeman, P.D., 6524 Copper Field Road, Baltimore, MD 21209. Work number (301) 792-4022.

USED METAL RX FILES. For sale. Good condition and plenty on hand. Call (301) 655-2060.

PROFESSIONAL PHARMACY Don't miss this excellent opportunity to be your own boss in a professional atmosphere. This prescription oriented pharmacy in the Baltimore Metropolitan area offers clinic hours, an attractive income, and the vehicle to practice pharmacy the way you were taught. Financing available to qualified applicants. For more information write: Jan Patrick, 1100 N. Lindbergh Blvd., St. Louis, Missouri, 63132.

PHARMACIST AVAILABLE 1989 Rutger's graduate moving to Maryland this month. Has hospital pharmacy experience and is looking for hospital employment. Contact Lili Barski at (201) 463-7712 or write at 95 Redbud Road, Piscataway, NJ 08854.

INTERNATIONAL PHARMACY OPPORTUNITIES for retail pharmacies. Do you receive foreign prescriptions? We translate, advise and ship medications via a worldwide network to individuals in foreign countries. Commissions paid for referrals. Contact Jerome Kostecki, International Medicine Consultant, International Pharmacy Exports/Imports, PO Box 272, Glenview, IL 60025 or call (312) 631-4348.

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The Maryland Pharmacist

VOL. 65 CONVENTION 1989 NO. 6

Nathaniel Futeral, P.D.
1989–1990
MPhA President

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET
BALTIMORE MARYLAND 21201
TELEPHONE 301/727-0746

JUNE, 1989 VOL. 65 NO. 6

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107TH MPhA ANNUAL CONVENTION

ELWIN A. ALPERN

This has been a very fulfilling year in my life to have served as your President. I realized from the start there would be many problems and obstacles to overcome. What I didn't know was how members working together for a common cause could literally move mountains.

I believe our Association is not only pointed in the right direction, but is well in mind and body. Our Headquarters has a new look: newly painted interior and exterior, the new window treatments supplied by SAMPA, the rearranged office spaces and the freshly sodded and landscaped exterior for openers.

An entirely new staff as follows:

Gregory J. Wood, Executive Director who is a pharmacist and attorney, and is married to a pharmacist.

David G. Miller, D.U.R director and editor of the Maryland Pharmacist. Dave is also a pharmacist.

Maribeth Porter, MPhA's Office Assistant.

Davida Jones, D.U.R. Administrative Assistant.

And of course, MaryAnn Frank, our longstanding Comptroller.

Financially we have been able to meet all our obligations.

MPhA has established itself in the Maryland General Assembly passing two important bills. HB338/SB730 required parity in copayment requirements between community and mail order pharmacy insurance benefits.

SB732/HB1299—Establishes in law the MPhA proposed physician dispensing regulations.

The passage of these bills was a major victory for the MPhA. A special thank you goes to Nathaniel Futeral and Arnold Davidov for their untiring efforts and constant vigil. Also a thank you to all the pharmacists in the state of Maryland contacted by Nathaniel Futeral who immediately contacted their legislators to rally our cause.

We have established a Survival Fund to ensure fair opportunities for all pharmacies in the market place. As of April 17, 1989, 103 pharmacies have contributed. With the help of Loewy/District and Drug House we have collected $60,650.00. Please stand up for your rights to survive and contribute.

Our Annual Convention has been streamlined to meet the demands of the members. One day of business meetings and plenty C.E. credits are available.

Our mid-year meeting was moved to a more modern and accessible location. We had more interest from the members and suppliers and realized almost $5,000 revenue, the previous high was only $700.00.

Thanks to the capable leadership of Ilene Zuckerman, our house speaker and chairman of the Technician Task Force, a survey was published to help direct our association in addressing this issue.

Under the direction of Dave Miller, the MPhA was selected to continue Drug Utilization Review Services. The planned contract period is February 1, 1989 and it will run for three years.

The Maryland Society of Hospital Pharmacists and the MPhA co-sponsored an educational effort about free condoms through the Medical Assistance Program. Thank you Paul Weidle, Pharm.D. at the University of Maryland Hospital for obtaining the $3,000 grant from the Ansel Company to print 1000 signs and cover letters.

Never was a new Executive Director thrust into the line of fire as rapidly as Greg Wood. With one ear attuned to the members concerns and the other ear attuned to the problems, rapid action was taken on 2 fronts. We won 2 rapid victories due to Greg Wood's bold and decisive actions. We managed to have the Blue Cross auditing dilemma defused. When Prudential Insurance Company and PCS slashed our reimbursement by 10%, communications were sent out, meetings called, and political pressure brought to bear. Our lead was followed by a major 2000 store drug chain. Once again, victory was ours and the 10% was reinstated.

I believe the association has had a good year. I would link to thank all those who helped make it happen, Greg Wood, Dave Miller, MaryAnn Frank, the Board members, Committee heads, and especially my presidential advisor and friend, Melvin Rubin.

CONVENTION AND TRIPS COMMITTEE
Chaired By: Elwin Alpern

Our 1988 convention at the Sheraton in Ocean City attracted 41 exhibitors. It was fairly well attended. Those in attendance agreed that the food was good and plentiful. The continuing education was well organized by Maddie Feinberg and Ilene Zuckerman.

INCOME	
Registration	$13,444.50
Contributors	9,665.00
Exhibitors	15,530.00
Outstanding Income	741.15
Total Income of	39,380.65
Total Expenses of	23,224.80
Net Revenue of	16,155.85

Our trip to Aruba in January 1989 was well attended. The weather was ideal, and everyone was congenial. Our Continuing Education was courtesy of Eli Lilly and Company. The topic was "Diagnosis and Treatment of Ulcerative Disorders." We had 8:00 a.m. meetings to discuss the prior days reading assignment and completed 7 credit hours. The revenues realized were $1,175.00.

The next target was to upgrade the mid-year meeting. The Ramada Inn in Annapolis was selected and proved to be a wise choice. There were 160 pharmacists in attendence. Thanks to the support of drug companies and supplies we obtained a revenue of $4,900.00. The continuing education topics of New Drug Update and Maryland CDS Laws were well received.

For 1989's January mid-winter trip we are planning a cruise to the Caribbean on January 20–27, 1990. This was done by popular demand of the members.

NEWSLETTER COMMITTEE
Chaired by: Melvin Rubin

The Newsletter, which has been in existence in its latest reincarnation since 1976, was published 11 times during the past year—each month except for the usual combined summer edition. Dave Miller now puts the finishing touches on it before distribution and has added to the timeliness of news reaching members.

The primary purpose of the Newsletter is to provide necessary and helpful information to members related to economic and professional issues as well as providing you with synopsis of MPhA activities in and out of the office. Our efforts in these areas have apparently been well received by the membership.

Our secondary purpose of informing members of activities of local association activities continues to fall short because of lack of information coming to MPhA in time for publication. We also seek news related to members such as honors received and positions attained both in and out of pharmacy. Again, we seek your help to gather news which will be interesting to people in your area of the state.

PUBLIC AFFAIRS COMMITTEE
Chaired By: Phillip P. Weiner

The Public Affairs Committee met the usual number of times again this year. However, the Committee was not as active as in the past several years. It was not called upon by the Association to perform any function other than the weekly radio show.

All new programs on "Your Best Neighbor" are now interviews with persons allied to the Health Professions or who have the health of the public in their sphere of activity. When a show is aired that only contains me talking about a topic, it is an old tape.

My goal for 1989/1990 is to add a minimum of 12 new shows to the program and to be asked by the Association to perform whatever Public Affairs the Association deems necessary.

SURVIVAL FUND REPORT
By: Elwin Alpern
A LEGACY

It is not too often an opportunity presents itself to leave a legacy. However, because of the necessity of the Survival Fund, this opportunity has been mine.

Over 75 pharmacies plus many individuals have already contributed. I want to thank each of the following pharmacies for their support. The formula is very simple. Guide your hand when you approach the check book and write a check for $250.00 for each 50,000/year of the third party business you do.

Make checks payable to the MPhA Survival Fund and mail to the MPhA office at 650 West Lombard Street, Baltimore, MD 21201.

The fund is to insure the viability of community pharmacies in the state of Maryland in their efforts to serve the public. Initial activities would be aimed at unfair practices of some third party programs.

Each succeeding president will be charged to appoint a committee to guard and direct these funds. If this administration helps to reach a goal of $100,000, then the legacy will be put in place. Please help yourself and your profession for the future of pharmacy.

Call upon your suppliers and distributors for help in this endeavor. McKesson and Loewy/District have led the way with a donation of $10,000.00. They too want to be counted in this fight for survival.

As the saying goes, the ball is in your court. Let us see what you can do with it.

More than 300 people turned out for the 1989 MPhA Annual Convention in Ocean City. Be sure and mark June 17–22, 1990 for the 1990 Annual Convention. You won't want to miss it!

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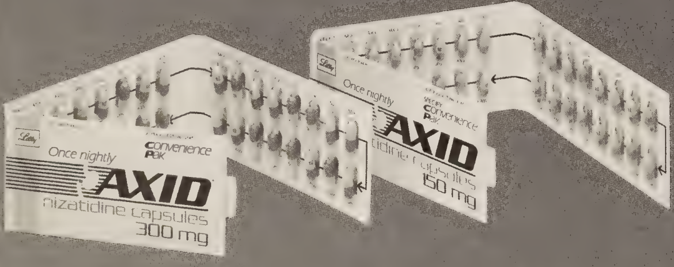

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[1] Data on file, Lilly Research Laboratories.

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Brief Summary

Consult the package literature for complete information.

Indications and Usage: Axid is indicated for up to eight weeks for the treatment of active duodenal ulcer In most patients, the ulcer will heal within four weeks

Axid is indicated for maintenance therapy for duodenal ulcer patients at a reduced dosage of 150 mg h.s after healing of an active duodenal ulcer. The consequences of continuous therapy with Axid for longer than one year are not known

Contraindication: Axid is contraindicated in patients with known hypersensitivity to the drug and should be used with caution in patients with hypersensitivity to other H_2-receptor antagonists

Precautions: *General* – 1. Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy

2 Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver. In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects

Laboratory Tests – False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine

Drug Interactions – No interactions have been observed between Axid and theophylline, chlordiazepoxide, lorazepam, lidocaine, phenytoin, and warfarin Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently

Carcinogenesis, Mutagenesis, Impairment of Fertility – A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice; although hyperplastic nodules of the liver were increased in the high-dose males as compared with placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high-dose animals was within the historical control limits seen for the strain of mice used The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement as compared with concurrent controls and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery are not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, mouse lymphoma assay, chromosome aberration tests, and a micronucleus test.

In a two-generation, perinatal and postnatal fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny

Pregnancy – Teratogenic Effects – Pregnancy Category C – Oral reproduction studies in rats at doses up to 300 times the human dose and in Dutch Belted rabbits at doses up to 55 times the human dose revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers – Studies conducted in lactating women have shown that <0.1% of the administered oral dose of nizatidine is secreted in human milk in proportion to plasma concentrations. Caution should be exercised when administering nizatidine to a nursing mother.

Pediatric Use – Safety and effectiveness in children have not been established

Use in Elderly Patients – Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among reported adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs < 0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to determine whether these were caused by nizatidine

Hepatic – Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients and was possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L) and, in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular – In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

CNS – Rare cases of reversible mental confusion have been reported

Endocrine – Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic – Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H_2-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported.

Integumental – Sweating and urticaria were reported significantly more frequently in nizatidine- than in placebo-treated patients. Rash and exfoliative dermatitis were also reported.

Hypersensitivity – As with other H_2-receptor antagonists, rare cases of anaphylaxis following administration of nizatidine have been reported. Because cross-sensitivity in this class of compounds has been observed, H_2-receptor antagonists should not be administered to individuals with a history of previous hypersensitivity to these agents. Rare episodes of hypersensitivity reactions (eg, bronchospasm, laryngeal edema, rash, and eosinophilia) have been reported.

Other – Hyperuricemia unassociated with gout or nephrolithiasis was reported Eosinophilia, fever, and nausea related to nizatidine administration have been reported.

Overdosage: Overdoses of Axid have been reported rarely. The following is provided to serve as a guide should such an overdose be encountered

Signs and Symptoms – There is little clinical experience with overdosage of Axid in humans. Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous median lethal doses in the rat and mouse were 301 mg/kg and 232 mg/kg respectively

Treatment – To obtain up-to-date information about the treatment of overdose, a good resource is your certified regional Poison Control Center Telephone numbers of certified poison control centers are listed in the *Physicians' Desk Reference (PDR)*. In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient

If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy Renal dialysis for four to six hours increased plasma clearance

PV 2096 AMP [013089]

Additional information available to the profession on request.

Survival Fund Contributions

Contributing Pharmacy

AID Drugs
Alpert Pharmacy
Apothecary, Inc.
Ayd Pharmacies
Balmer Pharmacy
Beachy's Pharmacy
Beckenheimers
Beeli's Pharmacy
Beltway Drugs
Boennings Pharmacy
Boonsboro Pharmacy
Carroll County Medical
Charlesmead Pharmacy
Cherry Hill Pharmacy
Cherry Pharmacy
Chestnut Pharmacy
Circle Drug
Citizen Pharmacy
Craig Drug Store
Dell's Pharmacy
Dolfield Pharmacy
Drug City
Eastpoint Medical Center
Edwards & Anthony
Edwards & Anthony (Harford)
Edwards Pharmacy
Edwards Pharmacy (Centreville)
Empire Professional Pharmacy
Englander Pharmacy
Fallston Medical Service
Family Pharmacy
Fenwick Pharmacy
Fibus Drug Store
Fields Pharmacy
Four Corners Pharmacy
Freedom Bergold Drug Stores
Halethorpe Pharmacy
Hereford Pharmacy
Holabird Pharmacy
Howard and Morris
Hudson Pharmacy
Irvin's Pharmacy
Irvington's Pharmacy
Jacksonville Pharmacy
James Drug Company
Jarrettsville Pharmacy
Jordan Pharmacy
Kayes AID Pharmacy
Keystone Pharmacy
Kirson Drug Company
Klein's Tower Plaza Pharmacy
Klotzman's Pharmacy
Kriger Drug Store
Levay Pharmacy
Lillich Pharmacy
Lykos Pharmacy
Maddie Feinberg
Marley Pharmacy
Mayer and Steinberg
McKesson/Loewy Drug Wholesaler
Medical Arts
Medicine Shoppe (Darlington)
Medicine Shoppe (Ritchie Hwy)
Medicine Shoppe (Route 40)
Medicine Shoppe/Havre-de-Grace
Medicine Shoppe/Marlyn Avenue
Millington Pharmacy
Mt. Washington Pharmacy
North East Pharmacy
Oakdale Pharmacy
Odenton Pharmacy
Osler Professional Pharmacy
Paradise Pharmacy
Park Avenue Pharmacy
Patterson Park
Pharmacy, Inc.
Potomac Valley Pharmacy
Powell Pharmacy
Prescription Parlor
Professional Arts Pharmacy
Professional Pharmacy Services
Purdum Pharmacy
Randallstown Prof. Pharmacy
Reynolds Pharmacy
Ritchie Pharmacy
Save More Pharmacy
Schmitt's Rexall Drugs
Seven Mile Lane Pharmacy
Star O Nevin's Drug Store
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The Medicine Shoppe/Hagerstown
The Medicine Shoppe/York Road
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Valu Food
Voshell's Pharmacy
Walsh/McCagh/Kellough Pharmacy
Washington Heights Pharmacy
Whiteford Pharmacy
Woodhaven Pharmacy
Woodlawn Pharmacy

Task Force on Pharmacy Supportive Personnel

Chairman: Ilene Zuckerman, Pharm.D.

At its 1988 Annual Convention, the MPhA House of Delegates passed a resolution for initiation of a task force to study the issue of pharmacy supportive personnel in Maryland.

On a national level, several national pharmacy organizations are in the process of studying this issue, or have taken formal positions. ASHP created a Task Force on Techincal Personnel in Pharmacy. Although the Task Force has been charged to 'think broadly, not restricting itself to institutional practice,' all its members have an institutional pharmacy background. At its last Annual Convention, the APhA House of Delegates passed a resolution endorsing 'the appropriate use of pharmacy technicians,' but opposing licensing, certifying, or registering technicians. NACDS favors the recognition and use of technicians, but opposes regulation, certifying, licensing, or setting ratios for technicians. NABP is in the process of studying which states license technicians. NARD currently has no position.

Currently, 3 states require licensing for pharmacy technicians (Illinois, Nevada, Washington), and 4 states offer certification (Illinois, Michigan, Massachusetts, New Hampshire). Nine states explicitly do not allow technicians in a community pharmacy setting; the remaining states either officially recognize technicians, or do not expressly forbid them (Maryland falls into this category). Maryland is one of 19 states that offer pharmacy technician training programs through community colleges, hospitals, or military, vocational, and high schools.

In 1979, the Association of Pharmacy Technicians was founded in California; the Association became a national in 1981.

In general, hospital, chain and mail-order pharmacy groups favor the use of pharmacy technicians, and independent community pharmacists oppose expansion of supportive personnel roles.

Since federal regulation of pharmacy supportive personnel is unlikely, it is up to each state to study the impact and implement (or not implement) new legislation.

This year's goal for the Task Force was to gather information and answer questions regarding pharmacy supportive personnel in Maryland. Questions the Task Force attempted to answer were: What is the status regarding regulations of pharmacy supportive personnel in Maryland? Are various aspects of pharmacy practice treated differently (e.g., hospital vs. community vs. long term care)? How are pharmacy supportive personnel currently being utilized in pharmacies in Maryland? What training programs exist for pharmacy supportive personnel in Maryland? How does the use of pharmacy supportive personnel affect the practice of pharmacy? How do Maryland pharmacists feel about the impact of recognizing pharmacy technicians?

The Task Force decided to conduct a survey of Maryland pharmacists. Results of that survey were presented at the MPhA Annual Meeting in February, 1989, and were published in the *Maryland Pharmacist*.

Our goal for the upcoming year is to further analyze the survey results and make recommendations for action to the MPhA Board of Trustees.

UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY DECEASED MEMBERS–SINCE JUNE 1988

Name	*Date(s) of Graduation*
James A. Barone	Ph.G. 1916
Meyer M. Baylus	Ph.G. 1926
Leon J. Bercovitz	Ph.G. 1934
Herman Bloom	Associate member
Gilbert Carouge	Ph.G. 1925
Patty W. Cheng	B.S. 1983
T. Nathaniel Cohan	Ph.G. 1914
Samuel C. Cohen	Ph.G. 1914
Don A. Collins	B.S. 1971
Joseph L. Combs, Jr.	B.S. 1938
Meyer Garfinkel	Ph.G. 1931
Herbert N. Goldstone	Ph.G. 1930, M.D. 1934
Samuel Higger	Ph.G. 1924
Douglas M. Kadan	B.S. 1971
Dean E. Leavitt, Ph.D.	B.S. 1954, M.S. 1957, M.B.A. 1964
Benjamin S. Levin	B.S. 1938
Nathan Levin	B.S. 1936, Ph.D. 1941
Philip Levin	Ph.G. 1933
Louis E. Oken	Ph.G. 1931
Stephen Panamarow	B.S. 1942
George Poltilove	B.S. 1943
Israel T. Reamer	Ph.G. 1924
Harry Rudie	Ph.G. 1930
Louis T. Sabatino	B.S. 1939
Milton C. Sappe	B.S. 1953
Herbert D. Schneyer	B.S. 1939
Emanuel V. Shulman	Ph.G. 1925, B.S. 1929, M.S. 1931, Ph.D. 1935
Albert M. Silverman	Ph.G. 1928
Alder Simon	B.S. 1943
Victor J. Sugar	B.S. 1950
James N. Trattner	Ph.G. 1928

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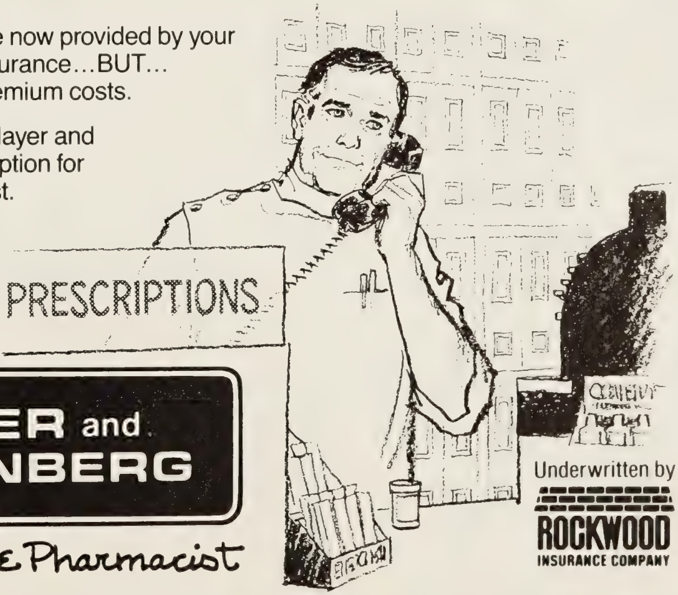

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This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Counseling Consumers on Dental Cleansing Aids Part I Toothbrushes, Floss, and Water Irrigation Devices

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. discuss the importance of proper oral hygiene in prevention of dental caries and periodontal disease;
2. present basic terminology used in discussion of oral hygiene;
3. describe the various types of toothbrushes, dental floss and dental irrigation devices and discuss utility and limitations of each; and
4. provide advice for consumers.

Objectives

At the conclusion of this lesson, participants will be able to:

1. determine the precise use for each type of toothbrush, dental floss and dental irrigation devices;
2. identify specific limitations for each of the dental cleansing aids;
3. choose the correct procedure for brushing, flossing and irrigation; and
4. demonstrate an ability to counsel consumers on toothbrushes, dental floss and dental irrigation devices.

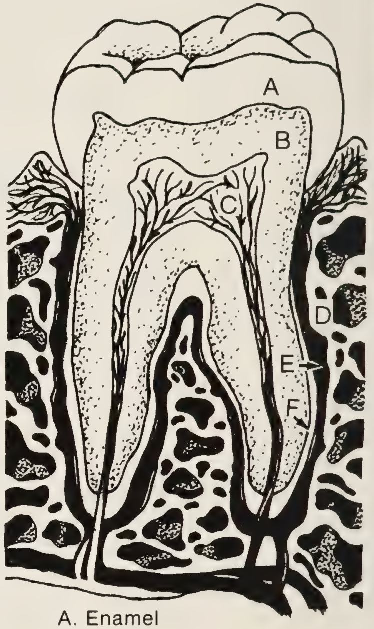
Figure 1. depicts the parts of a tooth. The **crown** is the visible portion and the **root** is below the gum line. A tooth is composed of four main parts: enamel, dentin, pulp, and cementum.

Enamel is a hard layer that overlaps the crown and protects the tooth.

Dentin protects the pulp and forms the greatest mass of the tooth.

Pulp contains the tooth's vascular and neural structures.

Cementum is the bonelike substance that surrounds the root. It helps anchor the tooth to its socket.



A. Enamel
B. Dentin
C. Pulp
D. Bone
E. Periodontal membrane
F. Cementum

Figure 1. Diagram of a tooth.

Dental Caries and Periodontal Disease

The presence of plaque at the junction of the gingival tissue and tooth is thought to be the most important extrinsic factor in initiating periodontal (gum) disease. Bacteria in plaque colonize rapidly. Within 24 to 48 hours of forming, enzymes and endotoxins are released. These result in gingival inflammation with bone and tooth loss.

Dental caries result from at least three interacting forces: 1) fermentable carbohydrates present in the mouth; 2) an acid-producing bacterial colony on tooth surfaces; and 3) the tooth surface itself. Bacteria convert carbohydrate into acid which causes demineralization of tooth enamel.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from
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Studies have repeatedly demonstrated that gingivitis can be prevented by a regular program of toothbrushing and/or flossing. The use of a toothbrush alone, however, has limited effect on the interdental (between the teeth) spaces.

In this lesson, the topic of oral hygiene will be examined. Toothbrushes, dental floss and dental irrigation devices will be emphasized. The correct use of these will be discussed as well as information to pass along to consumers. The topic will be continued in Part II of the series: *Dentifrices and Disclosing Aids.*

Toothbrushes

Toothbrushes are available in a wide variety of sizes and shapes. The American Dental Association (ADA) states that the ideal **cleaning area** (surface) of toothbrushes ranges from 1 to 1¼ inch in length and 5/16 to 3/8 inch in width. There should be 2 to 4 rows of bristles and 5 to 12 tufts (cloisters of bristles) in each row.

A **tufted-design** toothbrush contains 2 to 3 rows of 5 to 6 tufts. A **multitufted-design** brush has 3 to 4 rows of 10 to 12 tufts. For most purposes, multitufted brushes are more convenient because they have a greater cleaning area. On the other hand, tufted brushes may be more effective for hard-to-reach areas such as the lingual (inside, tongue area) tooth surfaces. The greater the number of rows of bristles, the longer it takes for the brush to wear out.

Toothbrushes are arbitrarily grouped as "extra soft," "soft," "medium," "hard," and "extra hard." Consumers accustomed to using a *hard* brush from one manufacturer may find that the bristles are harder or softer than desired, if they switch to a different brand because there are no official standards.

A soft or medium bristled brush is best for most purposes, assuming that the brush will be used with a dentifrice. Softer bristles are more flexible, permitting them to reach into the interdental spaces and beneath the gingival margin. When the brush will be used without a dentifrice, one with stiffer bristles may be better.

It has been reported that most Americans should replace their toothbrushes more frequently than they do. One survey indicated that 80 percent of brushes in use in the U.S. should be replaced. The report was based on annual sales of 50 million brushes. For a population of approximately 240 million, only one American in five (on the average) replaces his toothbrush within the year. Brushes should be replaced as their bristles begin to fray. This commonly occurs after about three months of use.

As bristles become worn, they soften. If a person waits too long to replace the brush, he may traumatize gingival tissue.

Overzealous brushing may lead to gingival inflammation, recession, abscess formation and lesions. People who forcefully brush have been reported to actually implant bristles into their gums. Damage is more likely to occur with hard bristles than soft. But bristle texture is less important than the technique used, as far as causing abrasive damage. Bristles with rounded ends are not necessarily better tolerated than bristles with non-rounded ends. With use, all ends become rounded.

Modern toothbrushes have bristles made of hog hair (*natural*) or nylon (*artificial*). Natural bristles are coarse and more prone to damage tooth enamel. Nylon is more resistant to breakage and easier to clean. But it is also more prone to soften and fray. The purchase of one type of bristle over the other is a matter of personal choice. Both afford nearly equal cleansing action.

The shape of the **brush handle** is not relevant to cleansing action. Individuals should choose a shape that is convenient for them and easy to manipulate. Some report that brushes with a contra-angle shaft (bent) stretch the lips less than brushes with a straight handle.

Interdental Stimulators. Some brushes have a rubber conical-shaped tip mounted on the end of the handle. The tip is intended to be gently inserted between the teeth and vibrated or rolled, to massage the gingiva. This action supposedly enhances blood flow into the area, increasing oxygen delivery and promoting waste removal.

Individuals with periodontal disease may be advised by a dentist to use these devices. Whether routine, unsupervised use of interdental stimulators promotes better health of gingival tissue is questionable. Their use should be discouraged, unless professionally recommended.

An **interdental brush** is intended to reach into the spaces between the teeth. These are normally missed by traditional brushes and brushing. Studies have shown that an interdental brush is more effective than a rubber cone stimulator in removing proximal plaque. A child's toothbrush may also serve the same purpose.

Toothbrushing Techniques

There is a correct method for applying toothpaste to a toothbrush. The dentifrice should be forced into the bristles of a toothbrush (Figure 2). In this manner, soft bristles of a multitufted brush form a "matting" effect, allowing direct contact between dentifrice and tooth surfaces. Placing it only upon the tips causes most of it to be lost.

Brushing with a rolling motion alone is probably not suitable for

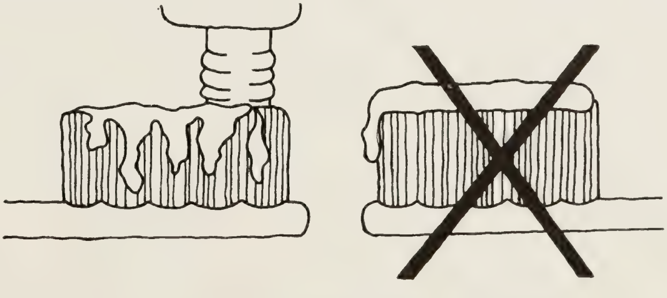

Figure 2. Correct method for applying toothpaste to a toothbrush.

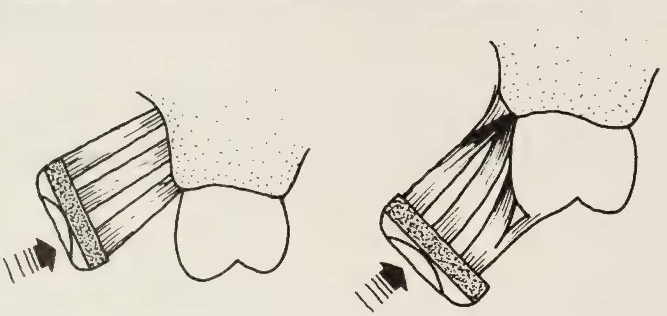

Figure 3. The sulcus cleansing technique (Bass Method) for oral hygiene

routine use. It is more tiring, and generates only intermittent pressure against the teeth. Long, horizontal movements may also be unsuitable since these reduce contact between the brush and interdental spaces and other crevices. But the exact stroke motion in brushing is not as important as the regularity and completeness of brushing.

One brushing procedure that is frequently recommended is termed the **sulcus cleansing technique** (or Bass Method). In this technique, the brush is held so that its bristles are at a 45° angle to the long axis of the teeth (Figure 3). A slight pressure is then applied to force the bristles gently into the sulcus space. The brush is then "vibrated" back and forth, for 20 strokes in each direction. Only a slight pressure is required since only the brush tips clean the area.

By this method, all or part of the surface of three adjacent teeth are cleaned concurrently. The brush is repositioned as often as needed, perhaps up to 40 times, so that all teeth are cleaned well. The sulcus cleansing technique affords complete coverage of all tooth surfaces. It also requires extensive personal motivation.

There are no conclusive data on how often an individual should brush. While some reports suggest that as many as five brushings per day are needed, others state that one cleaning each day is adequate. Most dental experts concur that the teeth should be brushed twice a day. One brushing should be thorough, and accompanied by a flossing.

Powered Toothbrushes

These toothbrushes have been available since 1939. They may be powered by battery or electricity.

Powered toothbrushes may use a back and forth motion, rotating, reciprocal arcuate (up-and-down), or a combination of brushing movements. The direction of movement is not as important as using the unit correctly.

Powered brushes are no more effective than manual brushes in removing plaque for most people. However, they are more convenient. Some studies have shown they produce less damage to tooth enamel and restorative material than manual brushes.

Persons who are poorly motivated in good oral hygiene and individuals who lack the dexterity to manipulate a toothbrush manually may do better with a powered unit. They are, therefore, recommended for persons with conditions such as cerebral palsy or multiple sclerosis.

Interdental Aids

It is well established that toothbrushing effectively cleans the buccal and lingual tooth surfaces. But brushing alone has a limited capacity to clean interdental surfaces. Adjacent teeth are usually close together and may be in direct contact with each other. A toothbrush cannot physically reach the sides of each tooth or crevice in the gums between the teeth. A number of interdental cleansing aids have, therefore, evolved. These include interspace and interdental brushes, floss, toothpaste, and irrigation devices.

Dental Floss. Dental floss is the most widely recommended item for cleaning these areas. The results of numerous studies have demonstrated conclusively that flossing reduces gingival inflammation.

Dental floss is available in waxed and unwaxed varieties. There is no evidence that either form is more effective for removing plaque. Many dentists recommend unwaxed floss since there is some evidence that a thin film of wax may be left on the tooth after flossing with the waxed variety. This wax may then act as a focus for further plaque accumulation. Additionally, some dentists believe that the filaments which comprise a strand of unwaxed floss spread when applied with pressure to the side of the tooth. This provides greater surface contact than would be possible with a single strand of waxed floss.

But people with closely spaced teeth may find unwaxed floss hard to slide into place. It also breaks easily. Struggling with it may cause injury to the gums.

To floss correctly, about 18 inches of floss should be removed from its container. The majority of one end of the strand should be wrapped around the middle finger of one hand, with the rest around the middle finger of the other hand (Figure 4). Approximately two inches should be left free.

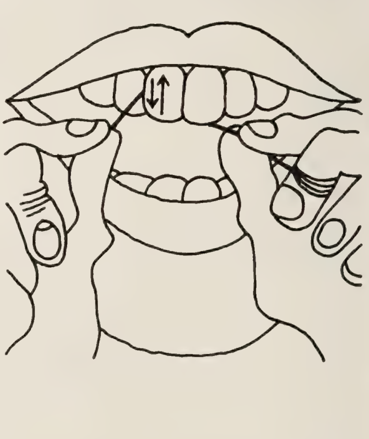

Figure 4. Proper method for holding dental floss and flossing the teeth.

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The floss is then guided into the interdental space with a sawing motion. It is curled around a tooth and gently pulled along its side, away from the gumline. As it becomes soiled, the floss is rewound to move to a new section. The procedure is repeated for all teeth. The floss should not be snapped or forced between the teeth. This may cause injury to the gums.

A dental floss holder can be used to hold the floss taut while inserting it into the interdental spaces, and moving up and down, across the tooth surfaces. The device is shaped in a "Y" configuration. Floss is stretched across the two arms. This is especially useful for the physically handicapped and other persons with poor manual dexterity.

Flossing may cause irritation and bleeding of the gums, especially when an individual first begins to floss. After flossing awhile, this is not a major problem.

Toothpicks. Special toothpicks are inserted into a holder. The user places the end of the pick on the tooth surface at the junction of the gingival tissue and tooth. It is then gently rubbed over the surface to mechanically remove the accumulated bacterial layer.

Water Irrigation Devices. These are useful to help dislodge and rinse away food and debris from between the teeth. Irrigation is also recommended as a cleansing aid for persons who wear orthodontic appliances. Irrigation supplements brushing and/or flossing, but it should never be used alone as a means to prevent plaque or cavity formation. And there is no advantage in using a commercial mouthwash in these devices rather than plain water.

Water irrigation has been studied as a means for removal of plaque. While the amount of plaque removed was minimal, using the device once a day did significantly reduce calculus (tartar) formation and gingivitis. It is believed that it may have affected the qualitative composition of plaque, which in turn reflected the quantity of calculus formed. Calculus is a hard, calcified material that contains dead bacteria. Its presence irritates the gums. There was no damage to oral soft tissues or dental restorations from water irrigation.

Another study showed significant reduction in plaque and calculus with irrigation, when compared to a control group. The main plaque-reducing effect was in areas where plaque accumulation was greatest, the interdental areas.

In another study where plaque removal with irrigation was measured, only 8 percent was removed from the teeth. Also, there was no evidence that irrigation diluted or removed microbial by-products.

The ADA Council on Dental Materials and Devices expressed the following opinion. It stated that pulsed water pressure cleansing devices ". . .may be useful as an adjunct to the toothbrush in removing loose oral debris and improving oral hygiene; however, there is no evidence available at this time that would support any claims regarding treatment or prevention of oral diseases."

Most studies on the subject show that water irrigation devices are safe, if directions are correctly followed. However, soft tissue damage can result when they are used improperly.

There is some danger to using a jet stream water irrigation device in the presence of periodontal disease. Irrigation may force debris into periodontal pockets or crevices of oral tissue. This may enhance bacterial growth and actually introduce bacteria into the blood.

Overview

Toothbrushes are available in a wide variety of sizes and shapes. At present, there are no definitive data available concerning the ideal design of toothbrushes. It is an area alive with opinion! Consumers should select a toothbrush that is comfortable to hold and use. They should also be told that not only is the frequency of brushing important, but thoroughness is also a factor.

The chewing of coarse, fibrous foods such as apples and carrots is often recommended to maintain good oral health. Also, these foods are excellent substitutes for sucrose-containing snack foods. No study has ever demonstrated that they prevent tooth and gum disease in the absence of brushing.

Pharmacists should encourage consumers to correctly use a powered toothbrush. Directions for use are generally included in the packaging. But these directions are often written in general terms, and do not stress the necessity of, or importance for, following a correct procedure in assuring that all tooth surfaces will be brushed well.

WE'RE FIGHTING FOR YOUR LIFE
American Heart Association

LOCAL PHARMACIST RECEIVES RECOGNITION AWARD

Marvin Freedenberg, P.D., President of Drug Lane Pharmacy Services, 11561 Edmonston Road, Beltsville, Maryland, is a recipient of the MSD Pharmacist Recognition Award. He is a resident of Silver Springs.

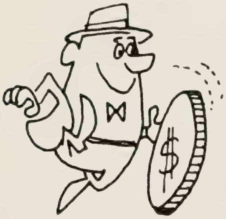
The award was established by Merck Sharp & Dohme (MSD), the U.S. prescription drug division of Merck & Co., to recognize business and civic achievements of pharmacists. Freedenberg was cited for his leadership roles in local organizations such as the American Heart Association and the American Cancer Society.

The award will be presented by Karen Ely of Merck Sharp & Dohme.

Commentary

As I was talking to an employee who was planning a trip to Disney World, I was also going thru my 3rd party correspondence. An idea hit me. Disney World was missing a truly terrifying attraction. I believe I have come up with an idea to help them recruit those who want a *real* adventure. The only problem I can see is that nobody would believe it could exist, and would probably be made a part of Fantasy Land. Only the pharmacists know it really does exist.

Glenn Lichtman



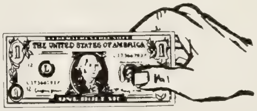
See Walt Disney World's Newest Attraction
Third Party Land

Some of the Rides and Attractions Are:

The Medicaid Ride: When you go on this ride, pack a lunch. You will actually take the same trip a Medicaid rx claim form takes on its way to being paid. The ride originates at a pharmacy, and travels a replica Medicaid payment center. You will spend a few leisurely weeks sitting with thousands of other claim forms, and then be carried by a very slow turtle to the rejection room. After another relaxing few weeks in the rejection room, you will be sent back to the pharmacy for no apparent reason. At the pharmacy, a frustrated pharmacist will see a red number written on your forehead, and try to match it up to a rejection list he has. He/she might curl you up in a little ball and throw you against the walls, cursing and stomping on you before he/she regains control. After a few heated phone calls on your behalf, you will once again be on your way back to the replica payment center. This might be a good time to eat the food you brought with you. As you start the longest portion of your trip, an exicting time awaits you! You get to sit on a desk and gather dust for 3 months. Eventually someone wil pick you up to use you as a napkin, and notice you are a claim form. You are cheerfully taken to the proper person for processing. Unfortunately, this person has left early to take an extended vacation in Bora-Bora.

The PCS Experience: This ride has changes frequently. You will get to be rejected many times much like the Medicaid ride, but at a faster rate of speed. Fortunately for you, during this time you can build up frequent flier miles. A portion of this ride takes place in Arizona. The most popular room in this attraction is the reduction room. In this part of the ride, a few uninformed people sit around deciding your worth. When you enter the room you may be worth 200, but in this room up to 20% of this can be discarded. Unfortunately we are not talking about pounds, but dollars. However, this procedure is absolutely painless to all involved with the ride with the exception of pharmacists. For this reason, we advise pharmacists not to go along with this ride. (A portion of the money spent here will be donated to a wholesaler who shall remain nameless but should know better than to allow this ride to operate, since they are one of the owners of it).

The Paid Ride: The name is a little misleading, and perhaps should be changed to the partially-paid ride. This is because a new feature that has been added, "The Reduction Room" (see the PCS experience for complete details). The feature that makes this ride exciting is you never know when you will enter the reduction room. It can be at anytime and you will never know about it until it is too late. Pharmacists with weak hearts and common sense should avoid this ride.



The Mail Order Ride: You will need a long time for this one, since rides are in increments of 3 months at a time. This is supposed to save money, but it never seems to work out that way. You usually end up wasting most of the trip when your doctor decides to change your destination, but the only one who loses is the company paying for your trip, so who cares? When you arrive at your destination, please wear your name tag. It can be very congested at the filling station, and mix-ups happen more frequently than anyone will admit. This occurs because the sales force for this ride brings in more visitors than the ride can accommodate safely. If the administrators of this ride would hire enough competent professionals this might not happen, but that would cost money and defeat the whole purpose of this ride. (Hint–Don't wear white round clothing. The people at the filling station see too many white round visitors and mix them up more frequently than others). One final word of caution about this ride: It does not seem to have to follow the safety rules or inspection procedures of any state. The administrators claim since the ride originates in one state and terminates in another, the rules and inspections of neither state apply to them.

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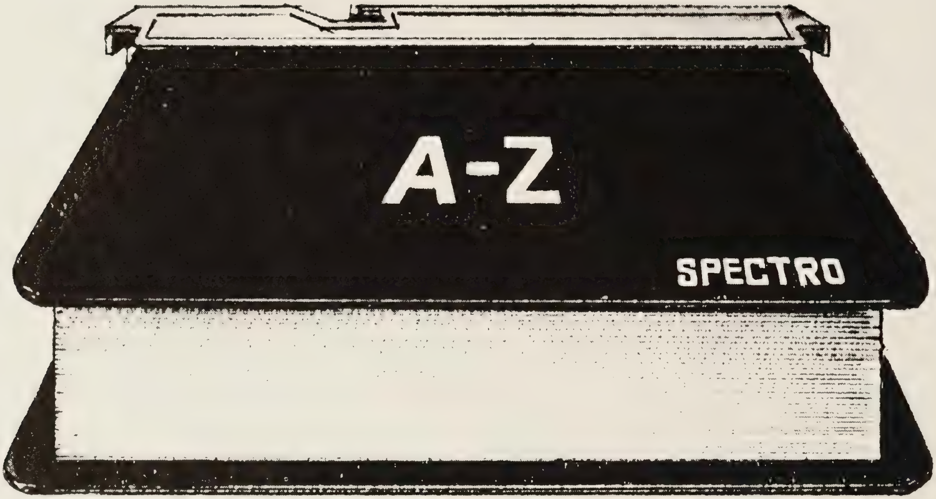

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This & That About Pharmacy

by Leon Weiner, P.D.

Brief News

On the night of Saturday, December 3, 1988, Baltimore's T.V. Channel 13 Eyewitness News featured Albert Katz (1962), who with his family, lit the first candles of Hanukah and explained the background of this Jewish Holiday. Katz owns Arundel Pharmacy in Glen Burnie, MD.

Gerald Schonfeld (1951) has been the owner of Monument Pharmacy in East Baltimore for over 27 years. In recent years, Jerry has earned an M.S. degree at the University of Baltimore and a Ph.D. degree at Union College in Psychology. He is now on the staff of a city community mental health clinic as a psychotherapist. Gerald and wife, Annette, are the parents of Steve Schonfeld who graduated from the Massachussetts College of Pharmacy in 1982.

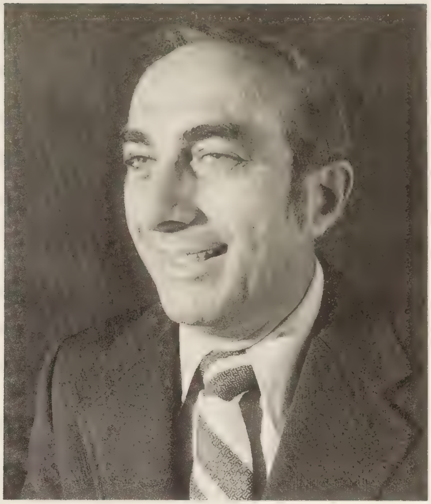
Mayer Handelman (1954) was one of the guest speakers at Pickersgill, the historic life care residence in West Towson. The seminar for high school students encouraged young adults to pursue careers involving senior citizens. Handelman is pharmacist-owner of Woodhaven Pharmacy on Joppa Road.

Love & Marriage

David M. (1954) and his wife Barbara Rombro take pleasure in announcing the engagement of their son Robert to Deborah Lynn Rubin. Dave is one of the owner-pharmacists of MacGillivray's Pharmacy in Baltimore City.

David (Dov) Rombro (1981) and his bride Abby were married October 30, 1988 in the Lloyd Street Synagogue in Baltimore. Today the Lloyd Street Synagogue is one of the Jewish Historical Society's two synagogues that have been designated as historic sites. Dov is one of the owner-pharmacists of MacGillivray's Pharmacy in Baltimore City.

Samuel R. Wachsman of Rockville recently got engaged to Kathleen E. Walter of Towson. Sam graduated from Richard Montgomery High School and is now attending U.M.A.B. School of Pharmacy.



Gloria and Jonas Yousem (1954) announce the engagement of their daughter, Sharie, to Randy Hyman, son of Rita and Herbert Hyman. Dr. Yousem is the owner of Village of Wild Lake Pharmacy in Columbia.

Michael Baer, son of Mr. and Mrs. Adolph Baer of Hagerstown will wed Gail Stoller, daughter of Dr. and Mrs. Stanley Stoller of Bethesda in September 1989. Adolph (1952) is the partner-owner of pharmacies in Hagerstown and Hancock, Maryland.

She is a pretty, red haired, part Irish young lady who met her future husband to be at a pub in Fell's Point on St. Patrick's Day. Now Melissa Kelch Christensen ('78) is well married, has 2 children and lives in Martinsburg, WV. Her husband, John works as a Marine Engineer. Melissa, originally from Canton, works for Dart Drug in Hagerstown and also for Patterson's Drug Store in Martinsburg, W. Va.

Recent Passings

The Winter 1988 issue of the Philadelphia College of Pharmacy Alumni bulletin list the following graduates who have recently passed away in Maryland:

1) Ernest I. Johnson, ('14), died in Catonsville, MD.
2) Bernard B. Kline, ('33), died August 21, 1987 in Silver Spring, MD.
3) Frank J. Gammino Sr., ('56), died in Baltimore, MD.

Condolences to Gerald Freedenberg, P.D. on the passing of his mother, Mae B. Freedenberg on December 25, 1988. Jerry, a member of A.Z.O. Pharmaceutical Fraternity, is the former owner of Irvin's Pharmacy in southwest Baltimore.

Phillip Levin ('33) died on December 13, 1988 of a massive heart attack. Dr. Levin, 75, lived in the Chevy Chase area and was employed by the Rite Aid Drug Company. Previous to that he had owned a pharmacy for 28 years.

Benjamin Samuel Levin ('38) passed away on February 24, 1989 at the age of 73. After graduation, Ben worked several years for Read Drug and Chemical Company and then switched to Purex Manufcturing Corporation in Washington, D.C. He then served in the Armed Forces during World War II. After discharged he worked for Libby Drug Store and then Bell Drug Company, both in Baltimore. He then opened up Richard's Pharmacy on Eastern Avenue in 1957 and remained there till 1973. Dr. Levin proceeded to work full time for Lutheran Hospital Pharmacy and continued till he retired in 1980. After that he worked part time for the same hospital. Among his survivors are his wife, Shirley, 2 children, 1 brother, and sister Evelyn Levin Yerzeroff and brother-in-law Benjamin Yerzeroff, both graduates of University of Maryland Pharmacy School in 1943. He was a member of the Maryland Pharmaceutical Association.

Louis E. Oken, ('31 PhG, '32 BS) passed away on February 26, 1989. He is survived by his wife Rosa and 6 children including David M. Oken, Univesity of Maryland Pharmacy School, 1958. After graduating, Lou worked approximately 15 years with the Read Drug and Chemical Company. He then purchased a pharmacy on Broadway (Oken's Rexall Pharmacy) in which he and his brother, Jack Oken, University of Maryland Pharmacy School 1946, were partners for 40 years. Jack and Lou also were partners in the Northern Rexall Pharmacy on Northern Parkway. Dr. Louis Oken retired from the business in 1980. He was a member of the Maryland Pharmaceutical Association.

Dr. Meyer M. Baylus, 82, passed away on March 18, 1989 as a result of a heart attack. He graduated from the University of Maryland Pharmacy School in 1926 and then went to the University of Maryland Medical School. He was an eye, ear, nose, and throat specialist for 56 years in the Baltimore area. Dr. Baylus was survived by his wife, Louise, 2 daughters, and 5 brothers.

Condolences to Paul R. Perzynski ('63) on the passing of his father Paul Peter Perzynski, Jr. on January 10, 1989. Paul, a former Eli Lilly retailman, now works for the Maryland State Department of Health.

Condolences to Marvin Goldberg ('65) on the passing of his mother, Rose Goldberg on December 16, 1988. Marvin is the Directorum of Alpha Zeta Omega Pharmaceutical Fraternity.

An Interview with Pharmacy VIP Murhl L. Flowers (Pharmacy Coordinator for Safeway Stores, Inc.)

Maryland Pharmacists Association (MPhA) takes great pride in interviewing Murhl Flowers (M.F.) of Safeway Stores, Inc.

MPhA: How did you become interested in Pharmacy and from which pharmacy school did you graduate?

M.F.: I graduated from West Virginia University in 1965. I started college majoring in Chemical Engineering and decided after 1½ years that engineering was not for me. I was very unsure about another career and a friend suggested that I go into Pharmacy. It seemed like a good idea even though I knew nothing about it and had never worked in a pharmacy or drug store. I didn't even know a Pharmacist. I have been very fortunate that my career choice has turned out very well.

MPhA: Can you give us your employment history?

M.F.:	1982–present:	Safeway Stores, Inc. . . . Pharmacy Coordinator for Eastern Division.
	1980–1982:	Temple Hill Pharmacy . . . Pharmacy/Manager
	1974–1980:	Ye Olde Apothecary . . . Pharmacist/Owner
	1972–1976:	Community Medical Center Pharmacy . . . Pharmacist/Owner
	1968–1972:	Morris Cafritz Memorial Hospital . . . Assistant Director of Pharmacy Services
	1965–1968:	Peoples Service Drug Stores . . . Pharmacist/Assistant Manager

MPhA: What about your personal life, your family, etc?

M.F.: I have been truly blessed with a wonderful family—my wife Regina, 20 year old daughter Kelly and 15 year old son Chris. Kelly is a junior at Riverdale Baptist School in Largo, MD, and looking toward a career in Aeronautical Engineering.

MPhA: What organizations, associations are you a member of?

M.F.:

- * Jaycees . . . President—Project Chairman—Officer
- * Greater Upper Marlboro Chamber of Commerce . . . President
- * Prince George's County Republican Club . . . President
- * Montgomery/Prince George's County Pharmaceutical Association
- * Maryland Pharmaceutical Association . . . Vice Speaker, House of Delegates, 1988–89
- * NACDS
- * South Arundel Optimist Club . . . President
- * American Pharmaceutical Association

MPhA: Can you tell us about your experiences with some of these groups?

M.F.: For more than 15 years I was actively involved in the Jaycee's at the local, regional, and state level. I was elected President of a very active chapter and had to develop an active plan for the year. Instituted comprehensive communication system; developed, staffed and implemented diverse programs and projects; promoted and completed programs within a limited budget. More than 100 projects were conducted, membership increased more than 50 percent, and I was recognized as one of the Outstanding Local Chapter Presidents in the Maryland Jaycees.

I've served as Chairman and founder of a Drug Abuse Speakers Bureau. We researched needs, secured cooperation of Jaycee members and appropriate components of the community and developed the content of the presentations. Our news releases and other promotional materials resulted in more than 375 programs presented to over 15,000 people within a three-year period. The project won several state Jaycee awards and many local awards. It also gained regional exposure by several organizations and members of the educational, medical and political communities.

During my membership in the Jaycees, I also held a number of other positions of responsibility. These included working on the Presidential Campaigns for Jaycee leadership at the state and national levels. I've organized support, developed strategies, implemented an action plan which incorporated the use of personnel, facilities and funds, and handled a wide range of promotional and public relation activities.

I played a key role in the revitalization of a local Chamber of Commerce and the business community it represented. I boosted membership, raised money for promotional and administrative needs, helped work on a revitalization plan and successfully coordinated the efforts of government at the town, county and state levels.

MPhA: Will you tell us about some of your honors and awards?

M.F.: Solon E. Summerfield Scholarship Award (Phi Kappa Psi Fraternity), Jaycee of the Month Award (numerous times), Spark Plug of the Year Award, included in the 1969 edition of the *Outstanding Young Men of America,* Outstanding Maryland Jaycee State Executive Committee Member, Key Man Award, Jaycee of the Year, JCI Senator #20008.

MPhA: Tell us about your experience with Safeway Stores, Inc.

M.F.: In 1982, I had the opportunity to take over the pharmacy program for the Eastern Division of Safeway, Stores, Inc. This division covers Maryland, Virginia and the District of Columbia. Our program has exhibited rapid growth, both in the number of pharmacies and in business. We have grown from 10 pharmacies in 1982 to over 51 locaions by December, 1988. Our program is built around the individual practicing pharmacist providing personal service to the customer. The rapid growth of the supermarket/drug combo operations is due to the effect of the one stop-shopping concept on the shopper of today.

MPhA: In your opinion, what are the problems facing pharmacy today?

M.F.: The major problem facing retail pharmacy today, in my opinion, is the increased number of third party plans. The lack of uniformity and parameters, as well as the inadequate compensation of many, makes it virtually impossible to participate efficiently and economically. The retail pharmacist in essence, is being told how to run a large portion of his business by non-pharmacist administrators. This will continue until the retail pharmacists, both independent and chain, refuse to accept those plans and proposals that are not in the best interest of the pharmacy profession. Only by working together can we stop this erosion of our margins.

The third party issue, along with mail order and dispensing physicians, must be faced directly by all of us in the profession. Never before has it been so vital for pharmacists to become actively involved in our associations so that we can develop a stronger and more organized voice. This is certainly my reason for participating in the MPhA. Last June, I was elected Vice Speaker of the House of Delegates. I look forward to working for the Maryland Pharmacists and I challenge each pharmacist in the state to become active in MPhA.

MPhA: What are your hobbies or other interests?

M.F.: Golf, athletics, coaching and officiating athletics, wine making, community involvement, working with young people.

Pharmacy Changes—January to June 1989

New Pharmacies:

Village Center Pharmacy
205 St. Mark Way
Westminster, MD 21157

Rite Aid #1792
5636 The Alameda
Baltimore, MD 21239

Giant Pharmacy #1198
9812 Falls Road
Potomac, MD 20894

Weis Pharmacy
3482 Emmorton RD
Abingdon, MD 21009

Arnold Professional Pharmacy
1509 Ritchie Highway
Arnold, MD 21012

Home Health Center
1308B S. Salisbury Blvd.
Salisbury, MD 21801

Fantle's Drug Store #307
275 Muddy Branch Road
Gaithersburg, MD 20878

Kaiser Permanente
Kensington-Concord
10605 Concord Street
Kensington, MD 20895

Valu Pharmacy #2
10 Stemmers Run Road
Essex, MD 21221

Rite Aid #672
Route 40 Highway Plaza
Aberdeen, MD 21001

Ownership Change:

Irvin's Pharmacy
4001 Annapolis Road
Baltimore, MD 21227

Seven Mile Land Pharmacy
4000 Seven Mile Lane
Baltimore, MD 21208
Formerly: Value Pharmacy

Closing of Pharmacies:

Charles County
Prescription Shop
Routes 5 & 301
Charles Professional Center
Waldorf, MD 20601

Kaiser Permanente-Summit
10500 Summit Avenue
Kensington, MD 20895

Thurmont Pharmacy
15 E. Main Street
Thurmont, MD 21788

Irvington Pharmacy
4123 Frederick Ave.
Baltimore, MD 21229

F & M Pharmacy #57
9457 Annapolis Road
Lanham, MD 20706

Best Care Pharmacy
800 Pershing Drive
Silver Spring, MD 20910

Rite Aid #2269
3458 Emmorton Road
Abingdon, MD 21009

New Location:

Rite Aid #331
1100 Light Street
Baltimore, MD 21230
Formerly: 1110 Light Street

ASCO Pharmacy
9515 Gerwig Lane
Suite 131
Columbia, MD 21046
Formerly:
8795 Colesville Road
Silver Spring, MD

Rite Aid 3837
Rt. 13 and Linden Ave.
Pokomoke City, MD 21891
Formerly: 1404 Market Street

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3. ARE YOUR HEALTH AND BEAUTY AIDS PRICES COMPETITIVE?
4. IF SO, ARE YOU TELLING YOUR CUSTOMERS?
5. HAS INCREASED THIRD PARTY PRESCRIPTIONS AND COMPETITION AFFECTED YOUR PRESCRIPTION DEPARTMENT PROFIT?
6. ARE YOU TIRED AND CONFUSED FROM SEARCHING FOR THE BEST SOURCE OF SUPPLY, AT THE BEST PRICE, TO FILL YOUR O.T.C. AND PHARMACEUTICAL NEEDS?
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Dickinson's Pharmacy

by Jim Dickinson

''The Independent Voice.'' The signs seem to be everywhere: as a nation and as a profession, we have been losing our independence and our independents. It's high time we did something about both.

When I was growing up in Australia in the 50s, everything had to be American or it was probably inferior. That went for cars, records, magazines, kitchen utensils, major appliances, clothing, breakfast cereal, sodas, hardware, cosmetics and, of course, medicines.

It was the same all over the world—except, perhaps, in America, where most folks were so tired of wars they were probably trying to forget that the rest of the world existed.

What a complete reversal in less than 40 years! The other day a bright glossy catalog arrived for a big Swedish furniture chain that's opening stores nationwide. When you go for a weekend drive in the country, you can't escape symbol of our national lack of confidence—three out of every five cars are imports.

We have become a nation of conspicuous consumers, and our group assumption is, if it's American-made, it's probably inferior. I have a theory about all this that involves every pharmacist in the country.

When America ''arrived'' in the world after licking the Nazis and their Axis partners, Japan and Italy, the good life went to our heads. Nationally we did what most families do when sudden riches come: we quickly shared it with our children.

They came to expect that the good life was just naturally ''there,'' as an entitlement. That meant there was no need—or at least, that there *ought* not be a need—to toil in the vineyards, and make your own way in the world without a lot of loving help.

With the boom in hugh, prosperous multinational corporations with large workforces, most Americans began to lose their individuality. Advertising helped reinforce the togetherness syndrome, keeping up with the Joneses, the peer group, and inter-dependency.

The assassination of our national leaders, the humiliation of Vietnam and Watergate, and the loss of the Challenger were all part of a cementing of a feeling of individual powerlessness across the land.

Today, we are used to surveys that show our young people want to avoid risk-taking and responsibility-acceptance. Pharmacy students do not aspire to open their own pharmacies.

A young pharmacist who works for National Rx told me at APhA's annual meeting in Anaheim: ''At least I don't have to worry about getting shot!''

You can understand that. It has become the spirit of our country.

Well, I say: Enough!

That's not living. That's dying—slowly, slowly, over a lifetime, perhaps, but still a kind of living death. You're not truly living life the way it's supposed to be lived if you're afraid to take serious, intelligent chances and reap the rewards that flow from risks.

A generation that's been coddled by parental indulgence and the comfort of peer and other support groups, may confuse the difference between risks and choices, and take shelter in group-think. A generation dulled in this way may be cheating its own children and their futures in a world that's full of new hazards; never was individual initiative and leadership more needed.

Fortunately, there are signs aplenty that a lot of people are beginning to realize this.

Entrepreneurship training is becoming important in education, with colleges around the country now adding it to their curricula. Some schools report that they're seeing a demand even from their students for this.

America's most admired corporation, Merck, tells us it got to be that way by encouraging entrepreneurship and individual risk-taking among its employees. Hundreds of others are following its example.

Where is pharmacy in these developments? The profession that grew out of entrepreneurship has been sadly lagging. Graduates owing $14,000 in student loans want to take the shortest direct route to Walgreen's or Rite Aid.

You can understand that. But ''independence'' is a state of mind as well as an actual state of proprietorship.

I think pharmacists need to get back to their heritage, both in their state of mind and in their place of business. Old skills need to be dug up, honed on new wheels, and put to work in the spirit of American revitalization.

We can do it. My newsletter, ''Dickinson's Pharmacy—The Independent Voice,'' Volume 1, Number 1, is out now and telling the practical, diverse story in eight pages every month.

This feature is presented on a grant from ''Dickinson's Pharmacy—The Independent Voice,'' an 8-page practical monthly newsletter available from Ferdic, Inc., P.O. Box 848, Morgantown, WV 26507-0848 at an annual subscription fee of $35.

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Your "Personal Earnings Estimate and Benefit Statement" Free from Social Security

By Dave Richardson
Social Security Manager in Baltimore

To serve you better now and in the future, the Social Security Administration has established a new system to provide workers, upon request, with a statement of their Social Security earnings history.

By completing the SSA form 7004 (6/88), "Request for Earnings and Benefit Estimate Statement," the worker will receive free from Social Security a "Personal Earnings and Benefit Estimate Statement."

The new statement will provide:

- a summary of the worker's earnings from 1937–1950
- an annual breakout of earnings from 1951–present, with the corresponding estimate FICA taxes, and estimates for retirement benefits as a reduced age, full retirement age, and age 70; and for survivors and disability benefits
- more realistic estimates using the worker's anticipated future earnings and recent unposted earnings, as well as including projected real wage growth
- the number of credits the worker needs to be insured for each type of benefit and the credits currently on record.

People who complete the new request form are asked to provide information about their recent earnings (which are not yet on record), their expected future earnings, and the age at which they plan to retire. This information is used in calculating the benefit estimates.

People can get a Form 7004 to request the new statement by calling toll-free 1-800-937-2000 or by writing to Consumer Information Center, Department 55, Pueblo, CO 81009.

The new statement serves as a tool for workers to verify their posted earnings and to learn the amount of estimated FICA taxes paid on the earnings. It also explains what they may expect in the way of Social Security protection so as to aid in their planning for their future financial security. And, it demonstrates that Social Security is an entire package of protection—retirement, survivors, and disability insurance.

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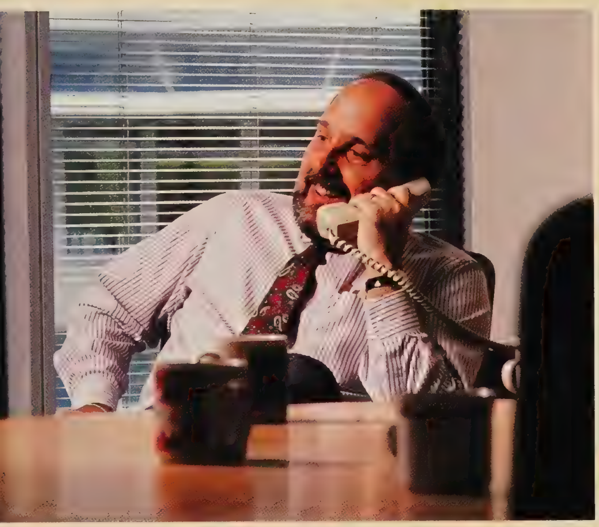

Marketing, one of the many reasons Boehringer Ingelheim Pharmaceuticals, Inc. is a leader in the domestic pharmaceutical market, is led by Jim Ueberroth, RPh, Vice President, Marketing (above, left). We have become a familiar name to pharmacists and physicians throughout the United States.

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MI-4190

Nurse Practitioners and Prescribing

Since the 1985 Attourney General's opinion, nurse practitioners, as authorized prescribers, have had the privilege in Maryland to prescribe medications including controlled substances. As most pharmacists in the state know few nurse practitioners are exercising this privilege. Sixteen nurse practitioners out of over 500 practicing in Maryland have DEA numbers.

Nurse practitioners practice under written agreements with physicians. The agreement provides a framework for a collaborative practice with a physician(s). This agreement describes the scope of the nurse practitioner's practice including the types of patients seen, the tests and procedures that can be ordered and the diagnoses that can be made independently. It also includes treatments and groups of medications that can be prescribed. Protocols for care are not a part of the written agreement. These agreements clearly stipulate the nurse practitioner's privilege to prescribe controlled substances in this practice setting.

The Maryland Board of Nursing's Joint Committee on Nurse Practitioner Agreements meets periodically to review in detail the appropriateness of the agreements. They review the educational preparation of the nurse practitioner to insure that she is practicing within her specialty. They also consider whether the physician relationship provides adequate time for collaboration and review of patient care. The Joint Committee submits their recommendations for approval of the agreements to the Maryland Board of Nursing.

The nurse practitioner who has been granted the privilege to prescribe controlled substances must contact the Maryland Division of Drug Control of the Department of Health and Mental Hygiene for an application. Once she has filed the application, the Division of Drug Control contacts the Maryland Board of Nursing before issuing a state controlled substance number. This is to insure that this practitioner's written agreement includes the privilege of prescribing controlled substances. The nurse practitioner is then responsible for procuring the application for the federal DEA number. There are no restrictions by the federal Drug Enforcement Agency on the schedules of controlled substances that a nurse practitioner can prescribe.

Nurse practitioners, by definition, are prepared as generalists in primary care. The focus of their education is health maintenance/promotion and treatment of common health problems and chronic diseases. Generally nurse practitioners practice in primary care settings in collaboration with primary care physicians. Nurse practitioners are specialized in the care of families, children, adults, and OB/GYN and geriatric patients. You will see nurse practitioners working in specialty practices where they use their skills and focus of primary care to assist in the care of patients with more complex problems. *The Maryland Pharmacist*'s article "Nurse Practitioners: Who We Are and How Do We Function" in the September 1986 issue may provide a helpful description.

This article was written with the helpful information of Evelyn Monroe, Consultant at the Maryland Board of Nursing and Charles Tregoe, Director of the Maryland Division of Drug Control.

Written by Shirley Van Zandt, CRNP, Adult, President of Council of Nurse Practitioners of the Maryland Nurses Association. She practices at Johns Hopkins Hospital in the Department of Otolaryngology—Head and Neck Surgery.

Special Thanks. . . .

To all the support of the following local organizations and their representatives.

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THIRD PARTY CHART: HMOs

HMO	Abbrev.	Acceptable sites	Unacceptable sites	Fee	Deduct.	Family card	MD list to follow	Auth. referral
CAREFIRST (301) 592-2500 Claims to: Health Service Plus Columbus, Ohio 1-800-888-9997	CF	All		$2.45 + net	.50–$3.00	No	CF	Yes
CHESAPEAKE HEALTH PLAN (301) 285-8000 Claims to: ClaimsPro Caterpiller Peoria, Illinois	CHP	02-03-13-15-20 30-31-33-34-42 43-50-66-68-70 71-75-76-77-78 80-81-82	50-60-83-85 Check these	$2.75 net	None	No	CHP List FS 500 Special Site Lists	Yes
FREESTATE Claims to: PHS 11833 Mississippi Los Angeles, CA 90029 1-800-421-2342	FS	All except: 0100 0901 0900 1100 2000 series		$1.85 $2.50 net (for 1500)	0–$5.00 GM–0	No	FS Mgmt List	Yes
HEALTHCARE 2000 (301) 296-5300	HC2	0-####-B 0-####-E	0-0030-Any (& 60) Letter	8% $1.00	$2.00–10.00 $2.00–10.00	Yes Yes	Clin. Assoc. HealthCare	No No
HEALTH-NET Claims to: PHS 11833 Mississippi Los Angeles, CA 90029	HN	1000 Series 1500 Relate only to those sites Not SinaiCare HN		$2.25	$2.00	Yes	1000 Series 1500	Yes
HEALTHNET (301) 225-8440	HN	SC (SinaiCare)		$2.50	$2.00	Yes	SC	No
HOSPITAL HEALTH PLAN	HP	All		$3.00	$2.50	Yes	All MDs	Yes
KAISER PERM (202) 364-6727	KP	All		$3.00	$ .00 Balt $6.00 DC $3.00 Medicare		KP	Yes
MEDICARE 1ST Same as CareFIRST	MC	All		$2.45 + net	$3.00–$5.00	No	CF	Yes

Notes: Series means all numbers which start same as 1000, 1001, 1002, etc.
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Surgicals and DME not cov. on Rx programs
Some sites will allow you to bill them directly

NEW FREE STATE CARDS 3rd digit from left:
0) No Rx coverage
1) 0 copay/BC
2) 0 copay/no BC
3) 2.00 copay/BC
4) 2.00 copay/no BC
5) 5.00 copay/BC
6) 5.00 copay/no BC

Do Not Accept JOHNS HOPKINS HEALTH PLAN

Dental	Pat. ID format	Group mandatory	Oral contracept diaphragms	OTC	Inj. syringes	Insulin on Rx	Misc.
If Pt. has rider	6 Digits Top Left Do not use Social Security #	Yes	If card has "C"	No	Inj—Yes Syr—No	Yes	Accept Pt. word on Referral MD. 34 Day Supply Use EasyClaim Transmittal Box
If Auth.	6 Digits/1 Letter Old Cards: ---- 9 Dig above name	No	If new card has "BC"	No	Yes	Yes	Accept Pt. word on Referral MD.
GM—Yes Others—Only if DDS on list	6 Digits—2 Dig	No	Up to 3 months (One fee)	No	Yes	Yes	Must use DEA # Can reduce plan # to 3 digits
No	Soc. Sec. #	No	Fee $ .00	No	Yes	Yes	Pt. pays for unauth. MD 80% reimbursement
No	Soc. Sec. #	No	Fee $ .00				
No—Pt. seeks reimbursement	Soc. Sec. #	No	Fee $2.25	No	Yes	Yes	Must use MD DEA # Pt. must pay for unauth. MD and receive 80% reimbursement
No	Soc. Sec. # (9 Digits)	No	Fee $2.50	No	Yes	Yes	Pt. must pay for unauth. MD and receive 80% reimbursement
Yes	Soc. Sec. # (9 Digits)	Yes	Yes	No	Inj—Yes Syr—No	Yes	Run by Maryland General
If Auth.	6 Digits—2 Dig	Yes	Fee $3.00	No	Yes	Yes	A.I.D. & M.I.P. Stores only thru D & P
	6 Digits Top	Yes	No	No	Yes	Yes	All groups in 7000 series—accept Pt. word on Referral

Watch for the special Third Party issue of The Maryland Pharmacist coming in November 1989. Information or suggestions for this issue should be sent to attention of the Editor at the MPhA office.

Things You Should Know FOR YOUR GOOD HEALTH

Caution - Motion Ahead

If you and your family are considering a summer trip this year, you should give consideration to a potentially stomach-wrenching problem — motion sickness. If it happens to you or someone in your family during a vacation, it could ruin a good portion of your relaxation time away. Motion sickness occurs when movement the body detects is not consistent with movement the eyes detect.

It has been said that this problem affects nine out of every 10 people at some point in their lives. Some people are known to be more susceptible to motion sickness than others. For instance, infants are generally considered to be nearly immune to motion sickness; however, children 2-12 years of age have a great susceptibility. Propensity to motion sickness usually decreases as one gets older and is reportedly uncommon after age 50.

This sickness can be caused by motion of almost any type — riding in a car, plane, train, on a boat, etc. Usually the initial symptoms of motion sickness include paleness of the skin, yawning, restlessness, and a cold sweat. These symptoms are followed by drowsiness and an upset stomach, culminating with excess salivation, nausea, and vomiting.

Motion sickness rarely results in an emergency situation, but can cause a problem for vacation plans. Treatment takes two forms, one for a person who is experiencing motion sickness at present and another for when one knows that they are susceptible to motion sickness and wants to try to prevent an attack.

If for instance your child begins to show the initial symptoms of motion sickness while traveling in a car, it is best that the child ride in the front seat, elevated so that he/she can look out the front window. It is best that the child try to focus on the stationary horizon rather than the bouncing inside of the car.

For those who know they are prone to motion sickness, prevention is usually successful with the prophylactic use of over the counter medications such as cyclizine and dimenhyrinate. These medications should be taken at least 30 minutes prior to travel because they are not very effective after the symptoms of motion sickness have begun. These medications should be taken with some precautions, however, because they can cause drowsiness and may be inappropriate for children or a pregnant woman.

Adults who are susceptible to motion sickness and whose jobs or lifestyles find them chronically traveling, may find some of the newer prescription products more convenient than those of the past. Small band-aid-type patches, which can be placed almost invisibly behind one's ear, will release small amounts of anti-motion sickness drug and, therefore, relieves the patient of the inconvenience of taking tablets. These patches are not appropriate for everyone.

For more information on motion sickness, its prevention and treatment, ASK YOUR PHARMACIST, a health care team member. It's For Your Good Health.

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TEST YOURSELF

Q

Given more time, will most debtors eventually pay?

A

NO A debtor's compulsion to pay a past-due account decreases with every passing day. Time has a way of dulling the value of the debtor's purchase to the point where they no longer feel obligated to pay for goods or services they bought in the "distant" past. A prompt and regular procedure for handling past-due accounts is your best bet for collecting the money that is owed to you.

TEST YOURSELF is one of a series provided by I.C. System, the company offering the collection program approved for use by our membership.

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ROXANOL UD
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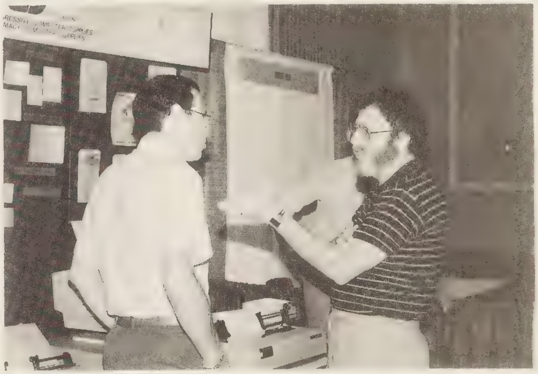
Roxane Laboratories has introduced a new unit dose package for Roxanol, morphine sulfate concentrated oral solution. Available in both 20mg and 30mg doses, twenty five doses are nested in a reverse-numbered tray for easy inspection.

About Your Medicines

USP is pleased to announce the publication of the expanded 5th edition of the consumer publication book, *About Your Medicines*. For more information or to order, call USP at (301) 881-0666, extension 686.

Crabs, chicken and more were available at the Annual Berlin Fire Hall Old Time Hoe Down at the 1989 Convention. 275 pharmacists and their families from Maryland and Delaware came to enjoy the festivities.



MPhA's Exhibition Hall featured free luncheon for all attendees on Monday and Tuesday at the 1989 Convention. More than 40 exhibitors came out to support our organization.

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Continuing Education Quiz

The Maryland Pharmacist **JUNE 1989**

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by August 1, 1989. A continuing education certificate for one contact credit) will be mailed to you within 30 days. Please type or print clearly.

Name ______________________________

Social Security Number ______________________________

Address ______________________________

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Is this program used to meet your mandatory CE? [ ] Yes [ ] No

Did this article achieve its stated objectives? [ ] Yes [ ] No

How long did it take you to complete the program? ____________ minutes

1. The portion of a tooth that contains its vascular and neural structures is the:
   a. cementum.
   b. dentin.
   c. enamel.
   d. pulp.

2. Which of the following is the most widely recommended and valuable aid for cleaning interdental surfaces?
   a. Cone Stimulator
   b. Dental floss
   c. Irrigation device
   d. Toothbrush

3. The term *tartar*, when used in reference to teeth, is synonymous with which of the following terms?
   a. Calculus
   b. Dentin
   c. Cementum
   d. Plaque

4. Of the following four forces, which is LEAST likely to be responsible for causing dental caries?
   a. Acid producing bacteria
   b. Demineralization of tooth enamel
   c. Fermentable carbohydrates
   d. Presence of plaque

5. Which of the following statements is true about irrigation devices?
   a. They are recommended for persons who wear orthodontic appliances.
   b. They are effective when used alone as a means to prevent plaque.
   c. They work better when used with a mouthwash versus plain water.
   d. They are effective when used alone to prevent cavity formation.

6. The most important concept relative to proper brushing of teeth is the:
   a. brand of toothbrush.
   b. direction of motion.
   c. thoroughness of brushing.
   d. toothpaste ingredients.

7. Which of the following statements is true?
   a. The shape of a toothbrush handle plays a major role in its cleansing action and efficiency.
   b. Interdental brushes have been shown to be more effective than rubber cone stimulators in removing proximal plaque.
   c. Artificial toothbrushes are coarse and more prone to damage tooth enamel than natural brushes.
   d. Natural toothbrushes are usually made of horse hair.

8. The brushing procedure whereby the brush is held at a 45° angle to the teeth and then vibrated back and forth is called the:
   a. gingival stimulator technique.
   b. periodontal prevention technique.
   c. sulcus cleansing technique.
   d. tooth fairy technique.

9. The substance that forms the greatest mass of a tooth is the:
   a. cementum.
   b. dentin.
   c. enamel.
   d. pulp.

10. Gingivitis and periodontal disease affect the:
    a. gums.
    b. lips.
    c. tongue.
    d. teeth.

Classified

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

PHARMACY RX ITEMS, broken containers, fast and medium movers for sale at reduced prices. Contact Preston Pharmacy at (301) 673-2318. Pharmacist closing store.

PHARMACY COMPUTER System for sale. 3PM 40/40, 5 years old, Best offer. Call Brian at Penn-Dol, (301) 669-2424.

EVERY SUNDAY MORNING at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the pharmacy public relations program, "Your Best Neighbor," the oldest continuous public service show in Baltimore.

PHARMACY FOR SALE. Well-established pharmacy on Eastern Shore of Maryland. Great hunting and fishing, close to beaches. $420,000 volume, 87% prescription and OTC. Call (301) 957-1648 after 8 pm.

PART TIME PHARMACIST to be utilized when regular pharmacist is on vacation and unexpected periods of illness. No weekends or holidays designated by the State of Maryland. Position is located at a State hospital. If interested, contact Emanuel G. Freeman, P.D., 6524 Copper Field Road, Baltimore, MD 21209. Work number (301) 792-4022.

PHARMACISTS REHABILITATION COMMITTEE HOTLINE is (301) 727-0746.

ATTENTION—HIRING! Government jobs—your area. Many immediate openings without waiting list or test. $17,840–$69,485. Call 1-602-838-8885. Extension 9494.

FDA HOTLINE FOR AIDS information is 800-432-AIDS.

ATTENTION—HIRING! Government homes from $1 (U-repair). Delinquent tax property. Repossessions. Call 602-838-8885 Extension: GH 9494.

ATTENTION—VEHICLES! Government seized vehicles from $100. Fords, Mercedes, Corvettes, Chevys. Surplus Buyers Guide. Call (602) 838-8885 Extension: A 9494.

HGP CLEANER by Coopervision wanted. Call (301) 655-2060.

PHARMACIST WANTED for full and part-time positions available. Benefits include health insurance, paid vacation and NO evening hours in a computerized independent pharmacy located on the Eastern Shore. Call Fred Beatie at (301) 742-1188 or (301) 742-0914 to discuss this exciting opportunity.

WELL ESTABLISHED professional pharmacy in central Texas university town. Average 120 Rx/day with yearly gross of $650,000. Computerized with small front end. Open 5½ days per week. Priced at $210,000. Reply to John R. Wilhelm at (915) 643-1886.

FOR SALE One used Drustar Model 3 Drug Cart with accessories plus six cassettes with drawers. Contact Ken Whittemore in Hagerstown at (301) 791-5220.

FOR RENT St. Thomas, U.S. Virgin Islands Condominium (weekly rental). Two bedrooms, two baths, overlooks the Caribbean on the beach. Ideal for two couples or family. Please contact: Dr. Steven J. Berlin, (301) 247-4770, evenings: (301) 252-7508.

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The Maryland Pharmacist

VOL. 65 LEGISLATIVE ISSUE, 1989 NO. 7

Maryland Pharmacy's Successful 1989 Legislative Season

THE MARYLAND PHARMACIST

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How Vital is a Lobbyist for an Association?

What About a Political Action Committee?

Q. What is the role of a lobbyist?
A. In brief, if an association intends to directly or indirectly work to support or defeat legislation, it must register as a lobbyist with both houses of the U.S. Congress.

Q. Isn't it true that any citizen can petition the government or testify before the legislature?
A. Yes. Such rights are guaranteed to all our citizens. In fact, even drug addicts, organized criminals, or for that matter reformed robbers of pharmacies, testify. A lobbyist, however, is one who attempts to affect the *actual outcome of legislation* (the when, whether and what), as distinguished from merely presenting a point of view, an opinion or a policy. Of course, even at hearings, the registered lobbyists—especially those associated with organizations with PACs—are most effective.

Q. How vital is it to the interests of an association's membership to be a lobbyist?
A. Let me put it this way. Can you imagine the reaction of a lawyer or physician upon learning that the American Bar Association or the American Medical Association or their respective Washington, D.C. offices were not permitted to lobby before the Congress? Similar shock would be expressed if these individuals learned that their PACs were planning to disband (or, getting very far-fetched . . . they had no PAC). After all, if an association is to effectively address and deal with the economic issues confronting its membership, both of these roles are essential.

Q. Does an association's PAC have an impact on legislation such as the competitive bidding proposal that was just defeated?
A. Certainly. A PAC allows the association to support Members who are pro-pharmacy and support the association's membership. It is also the ideal vehicle to indicate disapproval for who create problems for members of the association. After all, when it gets right down to brass tacks, money is the mother's milk of the American political process.

Q. In summary, how would you characterize the value of these two memberships benefits in Annapolis?
A. Let's put it this way. Not having them would be similar to finding oneself in a boxing ring without arms . . . you couldn't even try to defend yourself, or in this case defend your members, against attack from foes of pharmacy such as those who tried to subject drugs to competitive bidding and repeal freedom of choice.

Nathaniel Futeral, P.D.
MPhA President

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Update on OTC First Aid Antibiotics

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, OH

Gossel

Wuest

Goals

The goals of this lesson are to:

1. review FDA's rulings on OTC first aid antibiotic products; and
2. discuss the pharmacology and therapeutics of antibiotics used topically to prevent skin infections in self-treatable cuts, scrapes and burns.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from
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Objectives

At the conclusion of this lesson, participants should be able to:

1. choose approved OTC antibiotics for preventing skin infections from minor cuts, scrapes and burns;
2. demonstrate knowledge of pharmacology and toxicology of antibiotics approved by FDA for OTC marketing;
3. select non-antibiotic active ingredients that can be combined with agents referred to in #2 above; and
4. exhibit an understanding of labeling required on OTC first aid antibiotic drug products, and how to properly advise consumers on their correct use.

This article discusses antibiotics that are safe and effective for preventing skin infections from minor cuts, scrapes, and burns. A previous article in this series entitled, "Self-medication of Topical Bacterial Infections" presented information on self-treatment of boils (carbuncles), folliculitis, furuncles, impetigo, and other pyodermas (pus-producing infections). It also included a review of the broad spectrum of potential uses for OTC antimicrobial agents ranging from antiseptics to surgical products to wound cleansers.

FDA has issued its Final Rule on OTC Topical First Aid Antibiotic Drug Products in March 1988, after considering the many and various comments that had been submitted since the agency published its tentative findings in 1982. Unless there are significant, documented disagreements with FDA's rule, it will become the official monograph by which all manufacturers of OTC antibiotic-containing products must abide beginning in 1989.

Background on Skin Infections

The skin affords an excellent barrier against invasion by the numerous pathogenic organisms that exist throughout the environment. Because of its multiple layers of nearly impervious keratin cells (the stratum corneum), bacteria can neither easily invade nor penetrate the skin. The slightly acidic pH (i.e., the skin's "acid mantle") resulting from secretion of sebum, sweat and fatty acids also inhibits growth and reproduction of bacteria which optimally grow in a slightly alkaline medium.

When the skin is broken, its protective barrier is removed, and pathogens can gain entry to the lower layers, and eventually into the systemic circulation. Bacteria most commonly involved and likely to cause severe skin or systemic infection include staphylococci, streptococci, and pseudomonas species.

FDA's Response to Submitted Comments

Only a few comments were submitted to FDA concerning its original proposals. Many were neither substantive nor documented. However, a number of comments led FDA to reverse their original position in some areas.

It should be clarified that the agency commented only on those antibiotics promoted for first aid treatment of small superficial wounds, such as cuts, scrapes and burns. All other OTC antimicrobials and self-medicable skin infections will be addressed by FDA at a later date.

In its final rule, FDA agreed with most of the concepts originally proposed by its advisory panel. Before self-medicating of minor wounds, the area must be thoroughly cleaned. Also, debris in the wound should be removed.

FDA had already ruled that the phrase *treatment of infections* will not be allowed on OTC topical antibiotic product packaging and labeling. Although there is evidence that these agents, most specifically ointments, act as protective barriers against further contamination of minor wounds and help prevent proliferation of microorganisms already present, there is insufficient evidence to prove that topically applied antibiotics actually heal wounds that are already infected.

Therefore, the official approved indication that can appear on labeling of OTC first aid antibiotic drug products is: *First aid to help prevent infection in minor cuts, scrapes and burns.* Alternatively, manufacturers can substitute the phrases *decrease the risk of, reduce the chance of, guard against*, or *protect against* for the term *prevent*. They can also use the phrases *bacterial contamination* or *skin infection* instead of just *infection*.

FDA will allow manufacturers to use the phrase *kills bacteria* in their promotional materials, but not in the official approved labeling. While acknowledging the term *kills* is familiar to the average consumer, it is misleading in that it implies that all bacteria are eliminated, when in fact, topical antibiotics only decrease the number of selected bacteria from the skin.

The final rule also emphasizes the warnings against improper use of these products. An OTC advisory panel noted that chronic or excessive application of topical antibiotics, especially to areas where systemic absorption is probable, should be avoided. The agency revised previously proposed directions for using first aid antibiotic ointments or creams to read: *Clean the infected area. Apply a small amount of this product, an amount equal to the surface area of the tip of a finger, on the area three times a day.*

For aerosol and powder dosage forms, directions are similar, with an exception. Since it is difficult to estimate the dosage of a spray or powder, the terms *spray a small amount of this product* or *apply a light dusting of this powder* will be used for them. In all three instances, the phrase *may be covered with a sterile bandage* can be included in the directions.

Warnings Required on First Aid Antibiotics

Specific warnings will be required for these products, including:

For external use. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites or serious wounds, consult a doctor; and

Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than one week unless directed by a doctor.

For the former warning, such conditions require medical supervision. In the latter situation, if the condition has not cleared in one week, professional intervention is warranted.

FDA-Approved Ingredients for OTC Topical Antibiotic Drug Products

FDA agreed with most of its advisory panel's recommendations and its previously published proposed rule. Several changes include deletion of gramicidin as an approved drug. Inclusion of combinations of antibiotics, and somewhat surprisingly, the permitting of local anesthetics to be used in combination with topical antibiotics in OTC products were proposed. FDA has traditionally been very conservative in permitting marketing of fixed combinations of more than one active ingredient. Each of these ingredients will be reviewed as follows.

Gramicidin, a polypeptide antibiotic, was removed from the list of acceptable ingredients. Although gramicidin's mechanism of action and spectrum of activity are similar to those of bacitracin, FDA's advisory panel could not substantiate adequate proof of safety and effectiveness when it was used alone or in combination with other antibiotics. At the time of publication of the final rule, no well-designed, double-blind studies on its use had been conducted. Until such investigation is undertaken, gramicidin will not be permitted for inclusion in OTC products.

Bacitracin, a bactericidal antibiotic, interferes with proper synthesis of bacterial cell membranes. Its spectrum of activity is similar to penicillin (i.e., mainly gram-positive). However, it has never shown the degree of hypersensitivity or resistance of penicillin. Bacitracin has, therefore, replaced penicillin for topical use.

Neomycin is a broad-spectrum aminoglycoside antibiotic. This agent acts by a number of mechanisms, including interference with cell wall development, bacterial enzyme activity, and intracellular respiration. Since some normally susceptible organisms (including staphylococci) may develop resistance to neomycin, it is often used in combination with bacitracin or polymyxin, or both, to prevent such occurrence.

When the advisory panel that originally reviewed OTC topical antibiotics presented its findings to FDA, it expressed concern about neomycin's potential to cause sensitivity. However, in its final monograph, FDA defined neomycin as safe and effective. The agency concluded that short term use of neomycin on minor cuts, scrapes, and burns would not cause problems.

FDA also stated that while ototoxicity has been reported from local application of neomycin, those treatments were for severe conditions in which large doses were used. Amounts proposed for OTC use on minor cuts, scrapes and burns should not be a problem.

Polymyxin is effective mainly against gram-negative organisms. Its mechanism is detergent-like. On entry into membranes of susceptible organisms, it destroys the linkage between lipid-protein-lipid structures which cause the organism to burst.

Since gram-positive organisms are so prevalent in dermatological infections, polymyxin is not considered to be an adequate antibacterial agent when used by itself.

FDA has approved polymyxin for OTC use only in combination with

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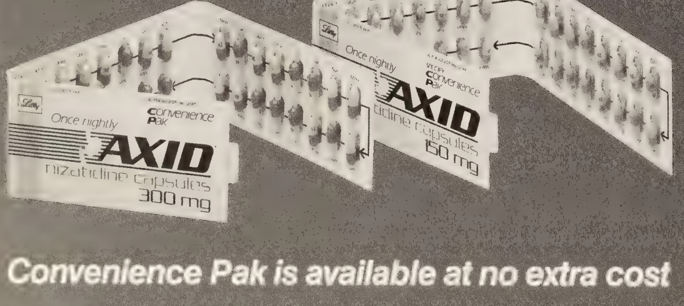

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Indications and Usage: Axid is indicated for up to eight weeks for the treatment of active duodenal ulcer In most patients, the ulcer will heal within four weeks

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Contraindication: Axid is contraindicated in patients with known hypersensitivity to the drug and should be used with caution in patients with hypersensitivity to other H_2-receptor antagonists

Precautions: *General* – 1. Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy

2. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects

Laboratory Tests – False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine

Drug Interactions – No interactions have been observed between Axid and theophylline, chlordiazepoxide, lorazepam, lidocaine, phenytoin, and warfarin Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system, therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

Carcinogenesis, Mutagenesis, Impairment of Fertility – A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice; although hyperplastic nodules of the liver were increased in the high-dose males as compared with placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high-dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement as compared with concurrent controls and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery are not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, mouse lymphoma assay, chromosome aberration tests, and a micronucleus test.

In a two-generation, perinatal and postnatal fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny

Pregnancy – Teratogenic Effects – Pregnancy Category C – Oral reproduction studies in rats at doses up to 300 times the human dose and in Dutch Belted rabbits at doses up to 55 times the human dose revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers – Studies conducted in lactating women have shown that <0.1% of the administered oral dose of nizatidine is secreted in human milk in proportion to plasma concentrations. Caution should be exercised when administering nizatidine to a nursing mother.

Pediatric Use – Safety and effectiveness in children have not been established

Use in Elderly Patients – Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo Among reported adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs < 0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to determine whether these were caused by nizatidine.

Hepatic – Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients and was possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L) and, in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular – In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects

CNS – Rare cases of reversible mental confusion have been reported.

Endocrine – Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic – Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H_2-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported

Integumental – Sweating and urticaria were reported significantly more frequently in nizatidine- than in placebo-treated patients. Rash and exfoliative dermatitis were also reported

Hypersensitivity – As with other H_2-receptor antagonists, rare cases of anaphylaxis following administration of nizatidine have been reported Because cross-sensitivity in this class of compounds has been observed, H_2-receptor antagonists should not be administered to individuals with a history of previous hypersensitivity to these agents. Rare episodes of hypersensitivity reactions (eg, bronchospasm, laryngeal edema, rash, and eosinophilia) have been reported

Other – Hyperuricemia unassociated with gout or nephrolithiasis was reported. Eosinophilia, fever, and nausea related to nizatidine administration have been reported.

Overdosage: Overdoses of Axid have been reported rarely. The following is provided to serve as a guide should such an overdose be encountered

Signs and Symptoms – There is little clinical experience with overdosage of Axid in humans. Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal Intravenous median lethal doses in the rat and mouse were 301 mg/kg and 232 mg/kg respectively

Treatment – To obtain up-to-date information about the treatment of overdose, a good resource is your certified regional Poison Control Center Telephone numbers of certified poison control centers are listed in the *Physicians' Desk Reference (PDR)*. In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient

If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance

PV 2096 AMP [013089]

Additional information available to the profession on request.

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1. Data on file, Lilly Research Laboratories.

NZ-2907-B-949315 [illegible]

bacitracin or neomycin. These combinations broaden the spectrum of activity significantly.

The **tetracyclines** are broad spectrum antibiotics effective against both gram-positive and gram-negative organisms. They act by interferring with enzymatic activity within susceptible organisms and preventing their growth and reproduction. Because tetracyclines are bacteriostatic rather than bactericidal, and because of the development of a high degree of resistance by gram-positive strains, their topical usage has declined considerably in recent years. While chlortetracycline and tetracycline are approved for OTC use as single entity ingredients, oxytetracycline has not been available by itself. Therefore, FDA approved its OTC use, but only when in combination with polymyxin. Table 1 lists FDA approved ingredients for OTC First Aid Antibiotic Drug Products.

Combinations of Antibiotics

Several combinations of two or more antibiotics were approved for OTC use as first aid products. Such drugs are combined to expand the spectrum of activity of each ingredient. For example, bacitracin is active against gram-positive organisms, while polymyxin is somewhat specific for gram-negative bacteria. Using them together expands the antimicrobial effectiveness of the product to most bacteria that invade skin structures.

The same is true for bacitracin and neomycin. Adding neomycin to the bacitracin/polymyxin combination extends the spectrum of activity even further. One additional approved OTC antibiotic combination is oxytetracycline and polymyxin. As stated previously, this resulted from oxytetracycline's OTC availability for many years and demonstration of effectiveness for use on skin infections. Oxytetracycline has not been commercially available in topical form except in combination with polymyxin. Therefore, this combination was also approved by FDA for continued marketing.

Combinations of Antibiotics and Local Anesthetics

When the original notice of a proposed monograph on OTC first aid antibiotics was published in the early 1970s, FDA excluded combinations with local anesthetics until data were submitted to show safety. Concern was expressed that the local anesthetic might mask symptoms of infection.

TABLE 1.

Safe and Effective OTC First Aid Antibiotics

Ingredient	Dosage Form	Strength
Individual Ingredients		
Bacitracin	Ointment	500 Units
Chlortetracycline	Ointment	30 mg/gm
Neomycin	Ointment	3.5 mg/gm
Tetracycline	Ointment	30 mg/gm
Combination Products		
Bacitracin/ Neomycin	Aerosol Ointment	500 Units–3.5 mg/gm 500 Units–3.5 mg/gm
Bacitracin/ Neomycin/ Polymyxin	Ointment Ointment Ointment Ointment	400 Units–3 mg–8000 Units/gm 400 Units–3.5 mg–5000 Units/gm 500 Units–3.5 mg–5000 Units/gm 500 Units–3.5 mg–10,000 Units/gm
Bacitracin/ Polymyxin	Aerosol Aerosol Ointment Powder	500 Units–5000 Units/gm 10,000 Units–200,000 Units/90 gm 500 Units–10,000 Units/gm 500 Units–10,000 Units/gm
Neomycin/ Polymyxin	Cream Ointment	3.5 mg–10,000 Units/gm 3.5 mg–5000 Units/gm
Oxytetracycline/ Polymyxin	Ointment Powder	30 mg–10,000 Units/gm 30 mg–10,000 Units/gm

Since then, the agency has reviewed comments suggesting that the above concern is unfounded because OTC antibiotics are indicated for first aid use, not for treatment of infections. It can be argued that such combinations should be approved because there are no documented data suggesting adverse reactions. The argument continues that pain often accompanies minor wounds, and therefore, such combinations should be approved. Antibiotics would help prevent infection, while the local anesthetic would help provide relief of pain.

FDA, therefore, reconsidered its decision and agreed that certain topical antibiotic/anesthetic combinations are safe and effective for self use. Part of this decision was based on the fact that combinations of antibiotics containing benzocaine or diperodon have been marketed for many years. And there have been no reported problems with masking infection or other objections. Therefore, first aid products may be marketed with a "suitable" local anesthetic as long as the product is properly labeled.

Approved indications include *for the temporary relief of pain/discomfort/itching associated with minor cuts, scrapes, or burns*, followed by the approved first aid antibiotic indications. This, then, is to be accompanied by the warning, *Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than one week unless directed by a doctor.*

There was one catch at the time FDA issued its final monograph permitting these combinations. The final monograph on OTC local anesthetic drug products had not yet been promulgated. Therefore, the agency stated that it would allow continued marketing of OTC products containing amide or "caine-type" anesthetics. Those that are being considered for approval as safe and effective OTC topical local anesthetic drug products are listed in Table 2.

Boil Treatment Drug Products

Shortly after FDA announced its final monograph on OTC first aid antibiotic drug products, the agency issued its Tentative Final Monograph

TABLE 2.

Local Anesthetics Suitable* for Combination with First Aid Antibiotics

Local Anesthetic	OTC Dosage Range
Benzocaine	5–20%
Butamben picrate	1%
Dibucaine (& HCl)	0.25–1%
Dimethisoquin HCl	0.3–0.5%
Dyclomine HCl	0.5–1%
Lidocaine (& HCl)	0.5–4%
Pramoxine HCl	0.5–1%
Tetracaine (& HCl)	1–2%

*Pending final approval by FDA

TABLE 3.

Proposed Boil Ointment Active Ingredients
Aminoacridine HCl
Benzocaine*
Bismuth subnitrate
Camphor*
Cholesterol
Extract of ergot
Hexachlorophene
Ichthammol*
Isobutamben
Juniper tar*
Lanolin
Magnesium sulfate
Menthol
Mercurous chloride
Methyl salicylate
Oil of sassafras
Oxyquinoline sulfate
Petrolatum
Phenol
Pine tar
Rosin cerate
Sulfur
Thymol
Zinc oxide

*Has some, but inconclusive proof of effectiveness. For all others, claims are not substantiated by proof of effectiveness.

on another group of drugs, OTC boil treatment drug products.

Boils (carbuncles) are referred to as pyodermas because pus is formed as the body's immune system attempts to ward-off the infective organism invading it. Previously, an OTC advisory panel concluded that there were no proven safe and effective drugs for treating boils. It noted that self-therapy is not desirable because improper treatment may cause the infection to spread. The panel stated that even though "drawing salves" (i.e., ichthammol, epsom salts, etc.) have been used for years, they have no proven merit in treatment of boils.

Available evidence showed that application of moist heat to the area of a boil is the most effective means for bringing it to a head. Sometimes the boil will draw spontaneously, or it can be carefully lanced and the fluid expressed.

Recurrent boils require systemic treatment with appropriate antibiotics. Since *Staphylococcus aureus* is the most common infective organism, a penicillin-resistant antibiotic is the drug of choice. The advisory panel considered the then available agents to be unproven remedies, and suggested their removal from the OTC market.

However, in its recent notice, FDA tentatively concluded that there may be a need for OTC boil treatment drug products, and manufacturers should be given an opportunity to provide additional data to support continued marketing of their products.

There was evidence that availability of these products directly to consumers to provide temporary relief from pain of boils may prevent them from attempting to manipulate or puncture them. This could spread the infection further.

Experts commenting to FDA also stated that most persons never seek medical attention to treat boils. They do not require the sophisticated and expensive services of a physician because the vast majority of boils are effectively managed by the body's normal host defenses. They are, therefore, basically self-limiting. These experts stated that it cannot be argued convincingly that topical boil preparations are more likely to lead to a need for surgery than are hot compresses or other home remedies.

Table 3 lists the previously available ingredients that had been included in OTC boil ointment drug products. FDA's advisory panel had concluded they were of unproven effectiveness, and therefore, recommended they be banned from further marketing for this purpose.

In its tentative final monograph, FDA switched benzocaine, camphor, ichthammol, juniper tar, magnesium sulfate, phenol and sulfur to the "some-but-inconclusive-proof" category. The agency announced that it would allow continued marketing of these products as long as clinical studies to establish effectiveness were ongoing. The deadline for submitting new data to prove effectiveness was set for March, 1989. In the event that any or all of these ingredients are proven to be safe and effective, FDA will require the following warning on their labeling:

Do not use on boils on the lips, nose, cheeks or forehead. Consult a doctor for treatment of boils in these areas; and

For external use only.

Counseling Consumers

Consumers should be advised to thoroughly cleanse the affected area before using an OTC antibiotic-containing topical first aid product. They should be instructed how to apply the product and how much. An extra thick layer of the product is not necessary. They should be counseled that signs of infection, such as extreme redness with swelling or pus, should be brought to the attention of a physician.

Summary

OTC antibiotic-containing topical ointment and cream products are safe and effective first aid remedies. Used appropriately, they can prevent infection from minor cuts, scrapes, and burns. A product containing a local anesthetic may be suitable when pain is bothersome.

OUR LOBBYIST REPORTS

Robin F. Shaivitz, Legislative Consultant

Maryland's pharmacists clearly enjoyed great success in 1989. MPhA resolved virtually every bill, in which we had an interest, in our favor. We passed the bills we liked, we killed the bills we didn't, and we amended the rest. This success demonstrates the influence of the pharmacy lobby. It also illustrates the soundness of our legislative strategy. MPhA's professional staff took a strong interest in public affairs, and they devoted ample resources—both material and personnel—to the lobbying effort. In addition, and of greater importance, MPhA's membership committed themselves to legislative success. Members made phone calls and wrote letters whenever asked. During the weeks before the Economic Matters Committee vote on mail-order, our pharmacists contacted EVERY commitee member, as well as many non-committee members.

Several other elements besides our broad grassroots support contributed to our victories. Certainly, we owe a great debt of gratitude to Nat Futerall, tireless chairman of our Legislative Committee. Also, the fact that there are pharmacies in most towns, and certainly one in every legislative district, makes pharmacy concerns statewide concerns. Since many pharmacists are prominent community members, they often have personal relationships with legislators. Finally, the status of pharmacies as small businesses, and MPhA's perceived and actual financial clout, helped as well. On to the bill summary:

SB 24, Health Insurance—Reimbursement for Pharmaceutical Products, sponsored by Sen. Dorman. *FINAL STATUS: UNF, ECONOMIC MATTERS. MPHA POSITION: NONE.* This bill would have mandated that all authorized prescribers be reimbursed at the same rate. Economic Matters killed the bill as political retribution against Sen. Dorman. See HB 338 for more on the substance of this bill.

SB 264, Health Occupations—Boards—Fees, sponsored by Sen. Blount for the Health Department. *FINAL STATUS: PASSED BOTH HOUSES. MPHA POSITION: SUPPORT.* This bill allows the various health occupations boards to set fees without legislation. Sen. Cade amended the bill on the Senate floor to mandate that the boards be self-supporting. The House removed this amendment.

SB 624, Home Care Employment Agencies, sponsored by Sen. Ruben. *FINAL STATUS: UNF, FINANCE, MPHA POSITION: NONE.* This bill would have regulated health professionals who provided care in a patient's home.

SB 652, Physicians—Ownership or Operation of a Medical Appliance Company—Prohibition, sponsored by Sen. Dorman. *FINAL STATUS: UNF. ECONOMIC AND ENVIRONMENTAL AFFAIRS. MPHA POSITION: SUPPORT.* This bill would have prohibited physicians from owning or operating medical equipment companies. The fact that this bill died in a committee on which Sen. Dorman serves as Vice-Chairman validates MPhA's decision not to pursue this year legislation prohibiting physician ownership of pharmacies.

SB 730, Insurance—Pharmaceutical Services, sponsored by Sen. Kasemeyer. *FINAL STATUS: PASSED BOTH HOUSES. MPHA POSITION: SUPPORT.* This bill prohibits insurance companies from charging policyholders a copayment or deductible for using local pharmacies if the insurer does not charge the policyholder the same copayment or deductible for using a mail order pharmacy. Also, if the insurer charges the policyholder for using a local pharmacy, then the insurer must charge the policyholder for using a mail order pharmacy.

SB 732, Dentists, Physicians, and Podiatrists—Dispensing of Prescription Drugs, sponsored by Sen. Della. *FINAL STATUS: PASSED BOTH HOUSES. MPHA POSITION: SUPPORT.* This bill takes the place of regulations which the Health Department should have published when the original physician dispensing bill passed. This bill stipulates that in order for a dentist, physician, or podiatrist to sell a prescription medicine, they must obtain a permit from their licensing board. The bill, also provides for certain labeling requirements for virtually any dispensing. Sen. Della sponsored this bill in large part because one of our members, Avi Pelta, contacted Sen. Della personally and appealed to him as a constituent to introduce the bill.

SB 794, Maryland Medical Assistance Program, sponsored by Sen. C. Riley. *FINAL STATUS: PASSED BOTH HOUSES. MPHA POSITION: SUPPORT.* This bill stated the purpose of the Medical Assistance Program, and directed the department to initiate some changes. Throughout the process of passing this bill, legislators noted how only the pharmacists had provided cost-containment suggestions to the committee.

HB 338, Insurance—Pharmaceutical Services, sponsored by Del. Taylor. *FINAL STATUS: PASSED BOTH HOUSES. MPHA POSITION: SUPPORT.* This bill originally was identical to SB 730. However, as a result of the death of SB 24, Sen. Dorman had the language from that bill amended onto HB 338. This does not hurt our bill, nor does it mean Governor Schaefer can't sign the bill.

Continued on page 11. . . .

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Continued from Page 9.

HB 636, Controlled Dangerous Substances—Anabolic Steroids, sponsored by Del. Rosenberg. *FINAL STATUS: UNF, JUDICIARY. MPHA POSITION: AGAINST.* This bill would have added anabolic steroids to the list of controlled dangerous substances. MPhA opposed this measure because we felt it should be an administrative, not legislative change.

HB 639, Residential Service Agencies, sponsored by Del. LaMotte. *FINAL STATUS: SENATE DID NOT APPOINT CONFERENCE COMMITTEE TO RESOLVE DIFFERENT HOUSE/SENATE VERSIONS. MPHA POSITION: SUPPORT AS AMENDED BY FINANCE COMMITTEE.* Very similar to SB 624, this bill would have regulated those providing medical care in a patient's home. MPhA, in concert with other health professionals, amended the bill to exclude those already licensed to practice by a health occupations board.

HB 815, Maryland Pharmacy Assistance Program, sponsored by Del. Thomas. *FINAL STATUS: PASSED BOTH HOUSES. MPHA POSITION: NONE.* The key provision of interest to pharmacists in this bill mandates that physicians must, if prescribing a brand name medication when a generic equivalent exists, write "BRAND MEDICALLY NECESSARY."

HB 836, Medical Assistance Program—Durable Medical Equipment-Price Review, sponsored by Del. Lutz. *FINAL STATUS: PASSED BOTH HOUSES. MPHA POSITION: SUPPORT.* This bill instructs the Medical Assistance Program to implement a price review when receiving claims for durable medical equipment.

HB 837, Medical Assistance Program—Durable Medical Equipment-Reimbursement, sponsored by Del. Lutz. *FINAL STATUS: UNF, ENVIRONMENTAL MATTERS. MPHA POSITION: SUPPORT.* This bill would have directed the Medical Assistance Program to reassess it's reimbursement for durable medical equipment.

HB 909, Prescriptions—Controlled Substances—Triplicate Prescription Blanks, sponsored by Del. Rawlings. *FINAL STATUS: UNF, WAYS & MEANS. MPHA POSITION: OPPOSE.* MPhA will study this proposal over the summer for possible action next session.

HB 910, Maryland Medical Assistance Program—Clomid-Prohibition on Reimbursement, sponred by Del. Kelly. *FINAL STATUS: UNF, ENVIRONMENTAL MATTERS. MPHA POSITION. OPPOSE.* MPhA opposed this bill because while we thought that clomid should be reimbursed, we felt that any change should be administrative, not legislative.

HB 1052, Maryland Medical Assistance Program, sponsored by Del. Ryan. *FINAL STATUS: PASSED BOTH HOUSES. MPHA POSITION: SUPPORT.* This bill is identical to SB 794.

HB 1299, Dentists, Physicians, and Podiatrists—Dispensing Prescription Drugs, sponsored by Del. Guns. *FINAL STATUS: PASSED BOTH HOUSES. MPHA POSITION: SUPPORT.* This bill is identical to SB 732.

HJ 16, Maryland Drug Information Center and Hotline, by Del. Forehand. *FINAL STATUS: PASSED BOTH HOUSES. MPHA POSITION: SUPPORT AS AMENDED.* This bill asks the University of Maryland Pharmacy School to establish a drug information center and hotline. With the help of Delegate and fellow pharmacist Donald Elliott, we amended the bill to remove the section calling for answering specific questions on drug therapy over the telephone.

Alumni Association Names Honored Alumnus

Clayton L. Warrington, Jr., class of 1958, is the recipient of the 1989 Honored Alumnus award from the Alumni Association of the University of Maryland School of Pharmacy. Mr. Warrington is a partner in Dugan/Farley Communications Associates, Inc. of Upper Saddle River New Jersey, a full service advertising agency specializing in health-care industry promotion.

After graduating and passing the Maryland State Pharmacy Boards in 1958, Warrington entered the United States Navy Officer Candidate School in Newport, Rhode Island and was commissioned as an Ensign. During 1959–62, he served in the U.S. Navy, Air Arm in both helicopter and jet attack squadrons in the 6th Fleet operating in the Mediterranean Sea. From 1962 to 1964, he was stationed in the Office of Naval Intelligence at the Pentagon. During this time he did graduate work at American University and participated in intensive training in computer programming and systems analysis with IBM. In 1964, he left the Navy as a full Lieutenant.

His career in marketing and advertising began in 1964 when he served as marketing manager at Pfizer Laboratories in New York City. In 1966, he moved to Dean L. Burdick Associates, Inc., a pharmaceutical advertising agency, as Vice-President and Account Group Supervisor. In 1971, Warrington became Senior Vice-President, Management Supervisor at Sudler and Hennessey, Inc., a division of Young and Rubicam.

Since 1974, Warrington has been one of five partners in Dugan/Farley Communications Associates, Inc. The firm employs over 150 people and ranks as one of the largest advertising agencies in New Jersey. In 1988 it had billings of almost $60 million. He serves as Senior Vice-President and Treasurer.

Warrington is married to the former Elizabeth Waizenegger of New York and has two sons—Clayton, III and John.

REP. PETE STARK CHALLENGES MULTITIER PRICES

On May 1 Rep. Fortney "Pete" Stark (D-CA) told pharmacy leaders that there is no reason for multitier prices for prescription drugs and that the federal government, as a purchaser of health care products and services under Medicare and Medicaid, will not tolerate the practice.

"I don't see any reason why there are multitier prices," said Stark, chairman of the House Ways and Means Health Subcommittee. "I think where we will have some impact is that we are not going to pay a multiple pricing structure as a government."

Multitier pricing, a form of discriminatory pricing, occurs when retail pharmacists are charged substantially higher prices for the same medications than nonprofit and for-profit HMOs, mail order pharmacies, hospitals, and others. The low prices afforded these entities are not based on the quantity purchased (volume discounts), and ultimately result in cost-shifting to retail pharmacists and higher prices for consumers.

Part of the problem stems from the Nonprofit Institutions Act, a Depression-era law that forgives price discrimination crimes that benefit true charities. It allows drug companies to sell their prescription drugs to nonprofit health care organizations at low cost while shifting the costs of the drugs to retail pharmacists and their customers.

Stark said that vigorously enforcing the unrelated business income tax on nonprofit entities would help to address the unfair pricing practices that pharmacists and consumers confront. "I would just suggest to you that some not-for-profit organizations are ripping off either the government or their members," he said. "There is an unrelated business income tax and if it were properly enforced, in my opinion, a lot of the practices that you're concerned about would end."

He noted that the federal government and the Health Care Financing Administration, which administers the Medicare and Medicaid programs, should ensure that retail pharmacists and their customers are not discriminated against. "It seems to me that if we impose on you a price structure that you have to be able to buy (prescription drugs) at the same price as anybody else," he said.

Stark briefed pharmacy leaders on his bill, the Ethics in Patient Referrals Act of 1989 (H.R. 939). The bill would prevent a physician from referring patients to a health care facility in which the physician has a financial stake.

He also said he will continue to support the legislative efforts of Rep. Ron Wyden (D-OR) to stop physicians from selling prescription drugs for profit. "The doctor should not be in the business of hustling pills," he said. "They're selling a professional service. I think you should have a clear-cut distinction between your profession and doctors."

Stark also urged pharmacists to continue to work with Health Care Financing Administration officials as implementation of the Medicare Catastrophic Coverage Act proceeds. "Without you, this program isn't going to work," he said. "Stay with us and help us correct it."

SENATOR PRYOR VOWS CONGRESSIONAL ACTION ON MULTITIER PRICING POLICIES

Sen. David Pryor (D-AR) has announced that his Senate Aging Committee would conduct a series of congressional hearings this summer to explore drug manufacturers' price increases. Placing the blame for drug price increases, which for several years have vastly outstripped the general rate of inflation, on pharmaceutical manufacturers' multitier pricing practices, Pryor said, "I think they're gouging the American public."

Multitier pricing, a form of discriminatory pricing, occurs when retail pharmacists are charged substantially higher prices for the same medications than nonprofit and for-profit HMOs, mail order pharmacies, hospitals, and others. The low prices afforded these entities are not based on the quantity purchased (volume discounts), and ultimately result in cost-shifting to retail pharmacists and higher prices for consumers. "It's unfair, it's discriminatory, and it's taking advantage of the most vulnerable part of our population," said Pryor.

"You're going to see a great deal of activity on this issue," said Pryor, who predicted committee action within six to eight weeks. "We are going to be hearing testimony from your organization because we feel that you are out there on a daily basis in the trenches; you're the ones who have to be on the front line trying to explain these cost increases to these people. They do not understand them, I don't understand them, and the Congress does not understand them, but it's you who bear the brunt of this discriminatory process."

Pryor said he would ask NARD to testify on the issue during the series of hearings he plans to hold this summer. "We are going to get to the bottom of it," he said. "We can make a very strong case. We have assembled some dynamite facts and figures on multitier pricing."

In response to questions from pharmacy leaders, Pryor said his investigation would also explore other activities by manufacturers that contribute to drug cost increases, including drug sampling and other promotions provided to physicians. "I think Congress will be ready to do something about it," Pryor said, noting that his committee could subpoena records of manufacturers to examine the costs of entertaining physicians, distributing samples, and other industry activities that contribute to drug price increases. He said his hearings would also explore to what extent the dramatically lower prices paid for some products overseas are being subsidized by American consumers.

Pryor is chairman of the Senate Finance Subcommittee on Private Retirement Plans and the IRS and a member of the Senate Finance Subcommittees on Medicare and Long-Term Care and on Health for Families and the Uninsured. The Finance Committee held hearings in 1987 that explored that direct link between discriminatory pricing policies and illegal prescription drug diversion, which led to passage of the Prescription Drug Marketing Act. Pryor is also chairman of the Governmental Affairs Subcommittee on Federal Service, Civil Service, and Post Office.

Discriminatory Pricing Coalition Seeks Equal Access to Prices for All Pharmacists

A joint task force made up of NARD, the national association representing independent retail pharmacy, the National Association of Chain Drug Stores (NACDS), and the American Pharmaceutical Association (APhA) is proceeding with efforts to ensure all of the nation's retail pharmacists and their patients equal access to pharmaceutical prices under the same terms now available only to others in the pharmaceutical marketplace.

Discriminatory pricing occurs when retail pharmacists are charged substantially higher prices for the same medications than for-profit and nonprofit HMOs, hospitals, mail order pharmacies, and others. The low prices afforded these entities are *not* based on volume discounts and ultimately result in cost-shifting to retail pharmacies and higher prices for consumers.

The joint task force is committed to seeking a legislative remedy that would make available to retail pharmacies the same prices now available to others in the pharmaceutical marketplace. Options for federal legislation are now being evaluated by the task force, and a nationwide consumer education program emphasizing the adverse impact of multitier prices on the public will soon be launched.

If you would like more information on the coalition's activities, call or write:

Joint Task Force on Discriminatory
Pricing Legislation
NARD
205 Daingerfield Road
Alexandria, VA 22314
703-683-8200

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Annual Report of the Maryland Board of Pharmacy 1988–1989

In compliance with the provisions as set forth in the Health Occupations Article Section 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable William Donald Schaefer, Governor of Maryland, the Secretary of Department of Health and Mental Hygiene, Adele Wilzack and to the Maryland Pharmacists' Association. This is the eighty-fifth report to the Governor and Secretary and the seventy-fourth report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the period May 1, 1988 to April 30, 1989. This report is also being submitted to the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

MEETINGS

During the year the Board held seventeen meetings, five of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for licensure of pharmacists. In leiu of the regular Board meeting in November, a Regulatory Review was held.

OFFICERS AND MEMBERS

The Board consists of the following officers and commissioners: Steve Cohen, President, Milton Moskowitz, Secretary; Ralph Small, Leonard DeMino, Theodore Litwin, William E. Adams, George Voxakis and Dorothy Levi. All of the officers and commissioners are registered pharmacists in the State of Maryland with the exception of Mr. Litwin and Mr. Adams who are consumer (public) members of the Board.

PERSONNEL

The staff consists of Roslyn Scheer, Executive Director; Elaine Schnaper, Secretary, Tara Bolling, Stenographer Clerk, and Karen Alder, Stenographer Clerk.

EXAMINATION

The Board conducted examinations for licensure of pharmacists during the year. They were held at the School of Pharmacy of the University of Maryland on June 28, 29, and 30, 1988 and September 27 and 28, 1988.

The applicants who were examined in June of 1988 were licensed in July, 1988 which is in F.Y. 1989. There were one hundred and twenty-five applicants for the Board in June 1988. One hundred and nineteen passed both the theoretical and practical portions of the examination and were licensed. Six failed the examination.

There were twenty-one applicants for the Board in September 1988 (F.Y. 1989). Sixteen passed both the theoretical and practical portions of the examination and were licensed. Five failed the examination.

Data relative to the June 1989 examination will be given in the next Annual Report.

The pharmacist licensure examination is given in two parts consisting of the following:

Part I—NABPLEX
Part II consists of:
  Laboratory
  Maryland Law
  Federal Law

The NABPLEX and the Federal Law Exam are obtained from NABP. The Maryland Law Exam and the Laboratory Exam were compiled by members of the Board. The Laboratory Examination requires the compounding of four prescriptions per applicant. The following table shows the number of pharmacists who were licensed by examination during the past ten years.

YEAR	NUMBER OF PHARMACISTS
1979–1980	180
1980–1981	183
1981–1982	100
1982–1983	116
1983–1984	92
1984–1985	92
1985–1986	109
1986–1987	105
1987–1988	121
1988–1989	135

As in the past, many pharmacists applied for reciprocal licensure in Maryland in order to accept positions with their employers who have stores in Maryland.

In all cases, an applicant for reciprocal licensure must appear for a personal interview. The entire Board must act on whether or not to grant licensure to such applicants, who must sign an agreement to comply with Maryland's laws pertaining to drugs and pharmacy.

The following table shows those granted licensure by reciprocity thus far during the 1989 fiscal year:

	REGISTERED BY RECIPROCITY		
NAME	CERTIFICATE NO.	STATE	DATE
Doris E. Carrion	11353	Puerto Rico	05-27-88
Evans T. Prieston	11354	Pennsylvania	" " "
Joe Dean Bullis	11355	Nebraska	" " "
Mary Ann Faulkner	11356	Indiana	" " "
Sabina Ofori	11357	District of Columbia	" " "
Donna Aileen Goldman	11358	New Jersey	" " "
Norman N. Nicholson	11359	New Jersey	" " "
Jacquelyne T. Ivery	11360	Virginia	" " "
Perry L. Mackroll	11361	Texas	" " "
Sampson Akom Asumadu	11362	Massachusetts	" " "
Frederick Adelbert Ellis	11363	New York	" " "
Wallace B. Pickworth	11364	Vermont	" " "
Patricia Capotosto	11365	Pennsylvania	" " "
Richard Leonard Macoviak	11366	Pennsylvania	" " "
Trinh Nguyen-May	11367	Texas	" " "
Brenda R. Jaffe	11368	New York	" " "
Betty Jane Lemley	11369	District of Columbia	" " "
Elizabeth Ann Shriver	11370	North Carolina	" " "
Anne Barbara Cropp	11371	Massachusetts	" " "
Marcel L. Vigneault	11372	Connecticut	05-27-88
Marsha Katherine Millonig	11373	Minnesota	06-16-88
Nathaniel Rodgers	11374	District of Columbia	" " "
Marci Dee Schentzel	11375	District of Columbia	" " "
Robert Yakimo	11376	Pennsylvania	" " "
Mary Jane Cole	11377	Indiana	" " "
Demetris Michelle Tatum	11378	District of Columbia	" " "
Roberta Perry Vining	11379	South Carolina	" " "
Jeanmarie Modresky	11380	Pennsylvania	" " "
Alba G. Spicer	11381	Puerto Rico	" " "
Bernard James Goodman	11382	Missouri	" " "
Cecelia Nathan	11383	Georgia	" " "
Olayemi A. Olabisi	11384	Delaware	07-19-88
Mary-Dawn Landsman	11385	Pennsylvania	" " "
Jerilyn K. Jacob	11386	New York	" " "
James Iverson Carver	11387	Virginia	" " "
Dugald James Brown	11388	West Virginia	" " "
Meltem Sukriye Unal	11389	Ohio	" " "
Fereydoun Mohtashemi	11390	District of Columbia	" " "
Pervez Aziz Siddiqui	11391	New York	" " "
Ajeh Ofuka Abung	11506	District of Columbia	08-11-88
Elliott H. Weiss	11507	Pennsylvania	" " "
Catherine A. Olson	11508	Illinois	" " "
Bette Rae Klingman	11509	Nebraska	" " "
Manubhai Asharam Patel	11510	Illinois	" " "
Joan Susan Korek	11511	Texas	" " "
Bashir U. Shaik	11512	New York	" " "
Anna-Marie Homonnay-Weikel	11513	Virginia	" " "
Deborah E. Kocinec	11514	New York	" " "
Samia Haddad Farah	11515	New York	" " "
Stephen Mark Lautman	11516	New York	" " "
Thomas Gerard Canty	11517	Texas	" " "
Sara Catherine Stiles	11518	Georgia	" " "
Yasin Mohammed Hussain	11519	Massachusetts	09-14-88
Karen Gradon McCann	11520	New York	" " "
Rosario Floresca Pura	11521	Rhode Island	" " "
Christopher Alan lames	11522	West Virginia	" " "
Kimberly Carol Portouw	11523	Wyoming	" " "
Mitchel J. Fielder	11524	District of Columbia	" " "
Stacy L. Campbell-Bright	11525	Kentucky	" " "
John Vincent Coruari	11526	Nevada	" " "
Alfred Charles Speyrer	11527	Louisiana	" " "
Paul Alan Michelson	11528	Connecticut	" " "
Madhuria Atul Keluskar	11529	New York	10-27-88
Dushyant M. Patel	11530	New Jersey	" " "
William V. Batts	11531	District of Columbia	" " "
Steven Sodipo	11532	District of Columbia	" " "
Mohammed Ahemed	11533	District of Columbia	" " "
Clement O. Nduka	11534	Texas	" " "
David W. Miller	11535	Iowa	" " "
William Lee Edward	11536	Pennsylvania	" " "
Catherin Annette Byrne	11537	Minnesota	" " "
Elise M. Hoffman	11538	Michigan	" " "

Beth Ann Vanderheyden	11539	Indiana	" " "
Dale N. Morton	11540	District of Columbia	" " "
Simeon O. Orekoya	11541	District of Columbia	" " "
Wayne Przygoda	11542	Missouri	" " "
Lisa A. Modesitt	11543	Missouri	" " "
Cynthia Anne Schwaiger	11544	District of Columbia	" " "
Elizabeth A. J. Hasegawa	11545	Michigan	" " "
Jemilar B. Adelakun	11546	District of Columbia	" " "
Kendra Keller Grove	11547	Tennessee	" " "
Angela Shaver	11562	Hawaii	11-16-88
Barbara Wood	11563	Ohio	" " "
Sara Donegan	11564	Rhode Island	" " "
Emily Beth Prince	11566	New Jersey	" " "
Gift Sunday	11567	Texas	" " "
Claire True	11568	Iowa	" " "
Jeanne M. Myers	11569	Illinois	" " "
Dilip Naik	11570	New York	" " "
Douglas B. Kent	11571	Pennslyvania	" " "
Andrew Harris Fox	11572	New York	" " "
Scott W. Hayes	11573	New York	" " "
Debra Joan Fox	11574	New York	" " "
Joel A. Berger	11575	South Dakota	" " "
Denis M. Hardy	11576	New Mexico	" " "
Marilyn Hardy	11577	New Mexico	" " "
Nancy Howell	11578	District of Columbia	12-13-88
Chung J. Kim	11579	New York	" " "
Monica A. Kopp	11580	Ohio	" " "
Ajay Patel	11581	New York	" " "
Ann M. Doherty	11582	New York	" " "
Michael J. Slavoski	11583	Pennsylvania	" " "
Theresa Limoges	11584	Ohio	" " "
Anna Rouse	11585	South Carolina	" " "
Lucien Tancil	11586	District of Columbia	" " "
Jeanne Klobusicky	11587	Pennsylvania	" " "
Gregory Joo	11588	Virginia	" " "
Lee Barker	11589	New Mexico	" " "
Susan M. Decorte	11590	Pennsylvania	" " "
Snehel C. Patel	11591	New Jersey	01-19-89
Segan Audu	11592	Texas	" " "
Ajay Patel	11593	New Jersey	" " "
Gregory Wood	11594	Ohio	" " "
John J. Pelosi	11595	Rhode Island	" " "
Alan L. Miller	11596	Pennsylvania	" " "
Scott F. Roser	11597	Ohio	" " "
Margaret Abangwa	11598	Pennsylvania	" " "
Ramachandrun C. Raju	11599	New York	" " "
Elizabeth A. Wade	11600	Texas	" " "
David W. Derrick	11601	Illinois	" " "
David L. Gardener-Wells	11602	Idaho	" " "
Godwin B. Odunze	11603	District of Columbia	" " "
Ronald J. Schneider	11604	New York	" " "
Vadlamani Kali Prasad	11605	Wyoming	" " "
Karen Reese	11606	Virginia	" " "
Stephan Wickizer	11607	Tennessee	" " "
Bruce Lingel	11608	New York	" " "
Peter A. Klein	11609	Pennsylvania	" " "
Shankar D. Popli	11610	New York	02-24-89
Michelle Dillahunt	11611	District of Columbia	" " "
Enah Umoren	11612	District of Columbia	" " "
Oliver Ike	11613	District of Columbia	" " "
Olufemi Adesanmi	11614	New Jersey	" " "
Donald Henderson	11615	Pennsylvania	" " "
Gregory P. Berezuk	11616	New York	" " "
Manzar B. Ghorbani	11617	District of Columbia	" " "
Jennifer D. Kelly	11618	Arkansas	" " "
Andrew C. Lord	11619	Virginia	" " "
Mark S. Price	11620	District of Columbia	" " "
Cassandra A. Gordon	11621	District of Columbia	" " "
Merlene P. Lockrage	11622	District of Columbia	" " "
William Marth	11623	Illinois	" " "
Susan Dowley	11624	New York	" " "
Lisa Zeveney	11626	Pennsylvania	02-15-89
Nayan S. Raval	11627	Illinois	03-15-89
Eke O. Okai	11628	Texas	" " "
Elemihe Uzomah	11629	District of Columbia	" " "
Donald G. Grilley	11630	Texas	" " "
Albert Grant	11631	Delaware	" " "
Yvonne Bolton	11632	South Carolina	" " "
Gail A. Dener	11633	New York	" " "
Joseph M. Buccine	11634	New Jersey	" " "
Marsha J. Ricker	11635	Ohio	" " "
Anita Austin	11636	Washington	" " "

Frances Greene	11637	Michigan	" " "
Hooshang Shanehsaz	11638	Delaware	" " "
Ranjit Keluskar	11639	New York	" " "
L'Tanya Holmes	11640	District of Columbia	" " "
Deborah L. Long	11641	Washington	" " "
Elsie Ejenole	11642	District of Columbia	04-19-89
Nancy A. Lisowski	11643	New Jersey	" " "
Terry D. Leach	11644	Ohio	" " "
Katrin S. Fulginiti	11645	District of Columbia	" " "
Arthur L. Nelson	11646	District of Columbia	" " "
Kenneth B. Zebooker	11647	Delaware	" " "
Marvin Crews	11648	District of Columbia	" " "
Kathleen D. Blake	11649	Massachusetts	" " "
Stephen E. Sussman	11650	Texas	" " "
Robert W. Kenney	11651	Pennsylvania	" " "
Vera Lynne Shaffer	11652	West Virginia	" " "
Abdul Haleem	11653	New York	" " "
Elaine S. Robins	11654	Virginia	" " "
Frances C. Fahnbulleh	11655	District of Columbia	" " "
John C. Lockard	11656	West Virginia	" " "
Pamela K. Boening	11657	Virginia	" " "
Theodore T. Weyandt, Jr.	11658	Virginia	" " "
Elaine F. Fellman	11659	District of Columbia	" " "
Deanna G. Nelson	11660	Minnesota	" " "

The following table shows the number of pharmacists granted licensure by reciprocity and the number who were certified to be licensed by reciprocity in other states during the past ten years.

Fiscal Year	Reciprocity	Certification
1978–1979	113	42
1979–1989	73	69
1980–1981	88	72
1981–1982	85	51
1982–1983	103	60
1983–1984	119	58
1984–1985	148	54
1985–1986	191	70
1986–1987	206	57
1988–1989	228	86
TOTAL	1551	694

The table shows Maryland gained 857 pharmacists by reciprocity during the past ten years.

PHARMACY PERMITS

New permits to operate a pharmacy were issued to eighty-seven (87) firms as of April 30, 1989.

Location	1988–1989
Counties:	
Allegheny	0
Anne Arundel	4
Baltimore	4
Calvert	3
Carroll	4
Cecil	0
Charles	1
Dorchester	1
Frederick	1
Garrett	0
Harford	3
Howard	3
Kent	0
Montgomery	14
Prince Georges	23
Queen Anne	0
St. Mary's	1
Somerset	0
Talbot	0
Washington	4
Wicomico	0
Worchester	2
County Totals	68
Baltimore City	19
State-Wide Totals	87

Of the eighty-seven locations that were issued permits, twenty-eight were name changes. New permits were issued reflecting the changes; however, there were no changes in the permit numbers.

PHARMACY WAIVER PERMITS

In June, 1987, regulations were promulgated under COMAR, Title 10, Subtitle 34, Chapter 17, allowing waiver of full service requirements for recognized pharmaceutical specialties. As of April 30, 1989, the Board issued nine (9) new pharmacy waiver permits as follows: four (4) in Baltimore City; and one (1) each in Harford County, Howard County, Montgomery County, St. Mary's County, and Wicomico County.

MANUFACTURERS PERMITS

New permits to manufacture drugs, medicines, toilet articles, dentifrices, or cosmetics as of April 30, 1989 were issued to three (3) firms.

DRUG DISTRIBUTORS PERMITS

The Board issued twenty-six (26) new permits to distribute prescription drugs as of April 30, 1989.

TOTAL LICENSES AND PERMITS

The total number of establishments licensed through the State of Maryland is 1,336 and the total number of pharmacists is 6,948 as of April 30, 1989.

LEGISLATION

The following bills which affect pharmacy either directly or indirectly were enacted by the 1988 General Assembly. These bills must be signed by the Governor to become effective.

SB 264 Health Occupation—Boards—Fees which will become effective July 1, 1989, will remove the fees set in statute and permit each health occupation board to set fees in regulation for the issuance and renewal of licenses and other services of the Board.

SB 732 Dentists, Physicians, and Podiatrists—Dispensing of Prescription Drugs alters certain provisions of law relating to the dispensing of prescription drugs by dentists, physicians, and podiatrists; requiring certain dentists, physicians, and podiatrists to allow the Division of Drug Control to enter and inspect their offices at certain times; requires certain dentists, physicians, and podiatrists to provide certain patients with a written prescription under certain circumstances and maintain certain files; prohibits certain dentists, physicians and podiatrists from directing patients to a single pharmacy and receiving remuneration for referring patients to a pharmacy; authorizes certain Boards to take certain disciplinary actions under certain circumstances; alters certain provisions of law relating to the dispensing of starter dosages of prescription drugs; altering a certain definition; repealing an exception to certain labeling requirements for starter dosages of medication dispensed by an authorized prescriber; defining certain terms; and generally relating to the dispensing of prescription drugs by certain dentists, physicians, and podiatrists.

HB 1299 Companion bill to SB 732.

SB 172 Permits—Cholesterol Testing requires that a person hold a permit issued by the Secretary of Health and Mental Hygiene under certain circumstances before the person may offer to provide a test to detect the amount of cholesterol in an individual's blood.

COOPERATIVE ACTIVITIES

The Board maintained cooperative activities with the State Department of Health and Mental Hygiene, the University of Maryland—School of Pharmacy, the Maryland Pharmacists Association, the Maryland Society of Hospital Pharmacists, the Chain Drug Group, City, County and State Police and all Boards and Pharmacy Schools throughout the country.

DISCIPLINARY ACTIVITIES

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, State of Maryland Courts and other State Boards of Pharmacy. The wide range of complaints varied in severity. Listed below are statistics concerning the types of complaints for the period of May 1988 through April 1989.

miscellaneous*	13
mislabeled prescriptions	4
incorrect drug dispensed	14
generic substitution	2
dispensing physicians	2
shortages of controlled drugs	3
communication	2
dispensing drugs without prescription	6
dispensing habits of pharmacist	11
fraud	3
professionally, physically or mentally incompetent	7
TOTAL COMPLAINTS	67

*Complaints are on pricing, cleanliness, professionalism, prescription blanks, store hours, medical equipment, duties of technicians, expired prescriptions, broken pills, advertising and security of drugs.

During the period of FY 1989, eighteen Orders were issued and distributed for public information involving thirteen pharmacists and one pharmacy. These include: 7 consent agreements (1 revocation with immediate stay and probation, 4 suspensions with immediate stay and probation and 2 suspensions); 1 order to terminate revocation of license and place pharmacist on probation; 1 order to stay the suspension and place pharmacist on probation; 5 full reinstatements; 2 emergency suspensions against pharmacist license; 1 emergency suspension against a pharmacy; 1 revocation of pharmacy permit.

During the period of FY 1989, seventeen pharmacists were charged with violation of the pharmacy laws.

Continued on Page 22. . . .

THE
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an ALCO HEALTH SERVICES company

ATTENTION
MR. INDEPENDENT RETAILER

BELOW ARE 7 IMPORTANT QUESTIONS THAT COULD EFFECT THE FUTURE OF YOUR PHARMACY.

1. IS YOUR CUSTOMER BASE ERODING DUE TO DEEP DISCOUNT COMPETITION?
2. ARE YOUR PRESCRIPTION CUSTOMERS BUYING THEIR HBA'S FROM YOUR COMPETITION? (CHAINS, MASS MERCHANDISERS, GROCERY STORES)
3. ARE YOUR HEALTH AND BEAUTY AIDS PRICES COMPETITIVE?
4. IF SO, ARE YOU TELLING YOUR CUSTOMERS?
5. HAS INCREASED THIRD PARTY PRESCRIPTIONS AND COMPETITION AFFECTED YOUR PRESCRIPTION DEPARTMENT PROFIT?
6. ARE YOU TIRED AND CONFUSED FROM SEARCHING FOR THE BEST SOURCE OF SUPPLY, AT THE BEST PRICE, TO FILL YOUR O.T.C. AND PHARMACEUTICAL NEEDS?
7. ARE YOU INTERESTED IN A TOTAL PROGRAM THAT WILL SOLVE ANY OR ALL OF THE ABOVE?

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SUPER SAVERS

THE DRUG HOUSE
BALTIMORE/WASHINGTON DIVISION
301-467-2780

PATRICK L. HRUZ
SALES MANAGER

DICKINSON's PHARMACY

by Jim Dickinson

Patients as pharmacy soldiers. Any politician will tell you that the public is fickle, and any retailer who's been left with overstocked merchandise will tend to agree.

Yet no matter how fickle public support for various causes and fads may be, no politician, business or profession can long survive without it. In a democracy, it's the power to move mountains.

For at least the last five years, pharmacists have been either second or first at the top of the scale of public trust. But as pharmacy's myriad daily problems seem to multiply, you might ask: What is that public support really worth?

In the northern California city of Eureka last January, a retired former state employee named Martha Smith set out, against heavy odds, to show that it might be worth a demonstration of blind cost-containment's ability to yield to better health care.

And across the country, in Richmond, Virginia, another member of the public, Joan Dent (secretary of the public employees' association), took up the same pro-pharmacy cause with the help of a registered nurse who had received a drug mix-up in the mail.

Neither woman's fight was over when this column went to press, but their early experiences provide inspiration for the establishment of similar grassroots efforts to overcome managed-care prescription programs that treat the public like pawns in some giant game of che$$.

The obstacles Martha Smith encountered in her campaign were daunting. When presented with a new, financially coercive mail-order drug "option" in her retirees' health program, she decided she simply was not going to be bullied that way.

But although her elderly friends facing the same ultimatum were verbally supportive, when push came to shove, all but four were afraid to get militant enough about it to join Martha in her telephone and letter-writing efforts.

One of Martha's ideas for opposing the coercive program roll-over into mail-order was to survey her local pharmacists—and that's when she ran into her second barrier. Eight out of ten simply did not return the survey questionnaire she and her group distributed—although they were all happy to grumble about mail-order when spoken to directly.

The third obstacle came in the health program's non-responsiveness to their phone calls and letters. Martha decided to enlist the support of the pharmacy services administrative organization, Pharmaceutical Care Network, who put her in touch with me.

I was able to send her a small mountain of documentation. As Martha went to work with her retirees' association leadership and made contact with state politicians, things slowly began to take a turn for the better.

After "forgetting" and "losing" two months of repeated requests that it supply, under the state sunshine law, a copy of the coercive mail-order contract, Martha finally obtained one in March.

Among other things, it showed that the mail-order company, Medco Containment Services, had guaranteed the equivalent of a $900,000 rebate back to the plan—on condition that during the 19-month life of the contract, covered subscribers increase *1,600%* from 98,800 to 1,595,620—or the $900,000 would be cut proportionately.

Martha then achieved a breakthrough with the editor of the state retired public employees' association newsletter—a full feature article on the controversy, provoking the admiration of many, including NARD executive vice president Charles M. West: "We totally support the objectives of Martha Smith's network in California which are freedom of choice and comparable safeguards for the consumer."

Now we have the ear of state politicians, retirees, organized pharmacy, and even federal officials. A petition I submitted for FDA regulation of all high-volume mail-order facilities brought an encouraging—and unusual—personal response from FDA Commissioner Frank E. Young in February, ordering "expeditious" agency review because of "important public health issues" raised in the petition.

Meanwhile, Joan Dent has secured mass-media publicity against her coercive mail-order "option"—in an election year. In March she met with state program officials and warned them her members would tolerate every cost-containment device in the program except the mail-order component—then she issued a news bulletin to those members, urging them to watch for, and report, mail-order mix-ups.

Both Joan and Martha are forward troops in what will be a consumer army to promote public health through better pharmaceutical care.

By using the patient's own support groups and lines of communication, pharmacy in turn may ensure that its concerns are honestly heard by those in positions of power who usually dismiss pharmacy's words as the "voice of economic self-interest."

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

Seven of these cases have been concluded (included in the above statistics), one case closed (deceased) and nine are still outstanding.

The Board has 3 additional outstanding cases from the previous year which have not been concluded.

Some pharmacists were convicted of violating more than one statute. Listed below are the types of violations.

(4)	Provides professional services while using any narcotic or controlled dangerous substance	1
(5)	Submits a false statement to collect a fee	1
(6)	Willfully makes or files a false report or record	1
(14)	Without first having received a written or oral prescription	5
(21)	Is convicted of or pleads guilty of nolo contendere	3
(20)	Is professionally, physically or mentally incompetent	1
(23)	Disciplined by a licensing or disciplinary authority of any other state	5
(12–410)		
	1. Operates a pharmacy so as to endanger the public health or safety	1
	2. Operates a pharmacy in violation of any standard specified in the Health Occupations Article	1
	3. Operates a pharmacy not otherwise in accordance with the law	1

FINANCES

All funds of the Board of Pharmacy are deposited to the credit of the Treasurer of the State of Maryland and disbursements covering the expenses of the Board are paid by voucher by the State Comptroller.

FINANCIAL STATEMENT

The Board of Pharmacy had revenues of $198,130 in 1987 and $211,595 in 1988. The Board of Pharmacy had expenditures of $138,309 in 1987 and $163,631 in 1988. The Board's budget was $173,100 for 1989 and is $182,191 for 1990.

REGULATIONS

The Board promulgated or amended the following regulations:

1. Continuing Pharmaceutical Education
2. Reinstatement of Expired Licenses for Pharmacists

At this time the Board is in the process of proposing for promulgation or amendment regulations concerning:

1. Formal Hearings
2. Examination for Licensure and Internship Programs.
3. Transfer of Prescriptions Between Pharmacies
4. Security of a Pharmacy Facility
5. Reporting Pharmacists' Mailing Address and Location of Employment
6. Pharmacy Equipment
7. Reciprocity Fees
8. Standards of Pharmacy Practice
9. Monetary Penalties
10. Reinstatement of Expired Licenses for Pharmacists
11. Closure of Pharmacies
12. Experience Required for Licensure by Reciprocity
13. Parenteral/Sterile Enteral Compounding

CONTINUING EDUCATION

The State Legislature passed into law mandatory continuing education (CE) requirements for pharmacists as of July 1, 1986. The regulations for Continuing Education were promulgated August 8, 1988. Preparation by the Board for implementation of these regulations is continuing until the September 30, 1989, renewal date. Pharmacists renewing at that time will be required to have documentation for fifteen (15) C.E. credits with programs attended on or after July 1, 1986 being accepted. For September 30, 1990 renewals, 30 C.E. credits will be required, also with programs beginning July 1, 1986 being accepted. After this first renewal, 30 C.E. credits will be required for every two-year renewal period.

The Board of Pharmacy selected a Task Force to develop the necessary operational guidelines for regulation implementation. This Task Force prepared information for the Board's Newsletter sent to all registered pharmacists, to assure that new graduates and transferring pharmacists from other states are informed of the continuing education requirement, and offer information to anyone calling the Board's office. The Task Force also defined programs that would be accepted for credit by designing forms to submit for requesting approval of a program or a provider. The Board's Task Force will periodically evaluate providers authorized in the regulations, as well as those programs and providers approved by the Task Force after promulgation of the regulations.

The Task Force will monitor the accumulation of credits by all pharmacists on a randomly selected sample of pharmacists annually.

SECRETARY-TREASURERS MESSAGE

The collective efforts of all commissioners have produced another year of accomplishments under the capable leadership of President, Steve Cohen. The president has also assigned special tasks to each Board member.

Dorothy Levi, our newest member, has accepted many responsibilities and is our designated "Continuing Education Requirements Specialist". Referral of questions concerning CE are directed to Dorothy.

Theodore Litwin, consumer member, has accepted as one of his responsibilities, quality assurance policy development for pharmacy practice.

Leonard DeMino, as the veteran member of the Board, helps the Board members understand the historical perspective of policy and rules of the State Government.

William Adams, consumer member, is charged with developing a "Bill of Rights" for pharmacy consumers.

George Voxakis, closely reviews the monthly inspections of all community pharmacies conducted by the Division of Drug Control.

Ralph Small, conducts the monthly reciprocity interviews of all reciprocal applicants and makes his recommendations to the Board at every meeting.

We are all pleased to report a very good relationship with Charles Tregoe, Chief, Division of Drug Control. He has assisted us in our investigations of improper dispensing practices and other pharmacy inspection matters.

Our two standing committees, Committee I and II, have now been renamed to appropriately indicate their purpose. They are the Licensing and the Pharmacy Practice Committees.

The Licensing Committee concerns itself with examinations, the preceptor experience program, and regulations.

The Pharmacy Practice Committee will be examining the role of technicians (supportive personnel) in pharmacies and the formulary of authorized substitutions.

Each Board member has attended informal meetings or hearings concerning complaints or other issues before the Board. We also appreciate the support given the Board members by Larry Goldberg, Assistant Attorney General. He has also helped us during the meetings and with other regulatory or legal issues.

There have been a number of issues that merited the attention of the Board. We are happy to say that the requirements for physician dispensing are now law and regulations will be promulgated by the Board of Physician Quality Assurance. The Board of Pharmacy revised a number of regulations initiated by a law requiring a Regulatory Review. Still to be discussed before the Board are wholesaler regulations and requirements for mail service pharmacies. Other issues of concern are distribution of drugs in correctional facilities and nursing homes. A special task force has been appointed by the President to develop regulations for the use of FAX machines for the transmittal of prescriptions.

1988 has been a busy and productive year with many issues still to be discussed and resolved. I am very pleased by the efficiency and cooperation of all the Board staff personnel. The Board especially thanks Roslyn Scheer for her efforts in compiling much of the information in this report.

Roslyn Scheer, who has been the Board's Executive Director for more than 10 years, was honored at a testimonial dinner. In her position as Executive Committee member of the National Association of Boards of Pharmacy, she brings a depth of understanding of pharmacy issues that helps the Board in its process of examining national and local pharmacy concerns. Maryland practices preventive medicine: handling problems while they are small or heading them off before they actually appear in the State.

All the commissioners actively serve on various committees appointed by the president. We have held eleven regular monthly Board meetings.

We were delighted to hold a farewell retirement party for Anthony Padussis, outgoing President, last July, 1988 on the Governor's yacht. It was an event we will always treasure.

This is now my second full year as Secretary to the Board and it has been a satisfying experience. I feel that we accomplished a great deal, but there is always more to be done. No matter how many new projects or issues are in front of us, we graciously and with humility accept the challenge to serve the citizens of Maryland.

It is my personal pleasure to present this optimistic and positive report to the Governor. I look forward to another satisfying year of accomplishments for the Board, staff, and myself.

Respectfully Submitted,

Milton Moskowitz
Secretary—Treasurer

Nicholas C. Lykos, MPhA member and former Treasurer receives a special award plaque from Pfizer Pharmaceuticals for filling 1 million prescriptions. Dr. Lykos is the owner of Lykos Pharmacy in Timonium and was recently featured in an issue of the Towson Times.

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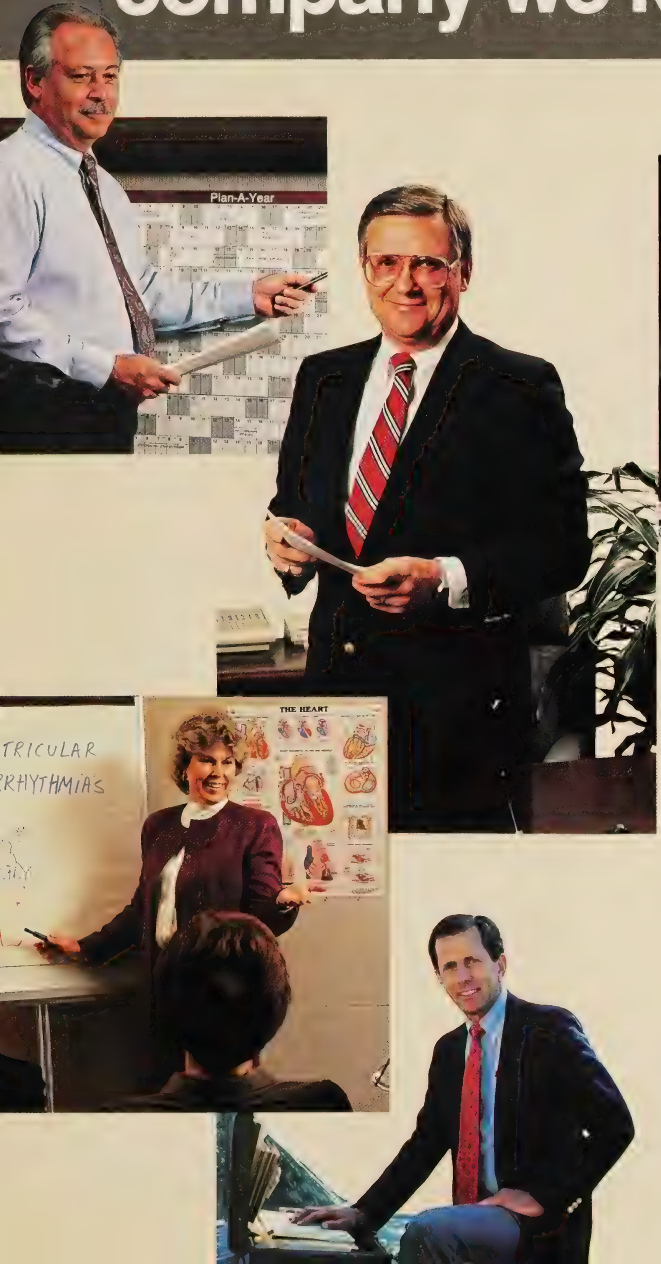

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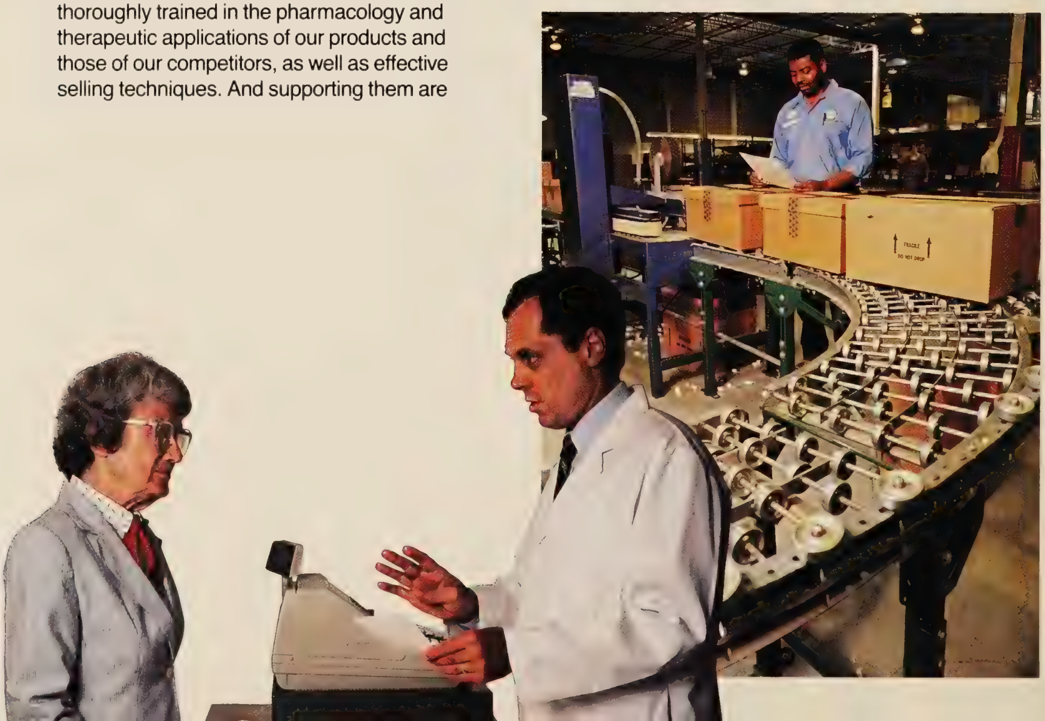

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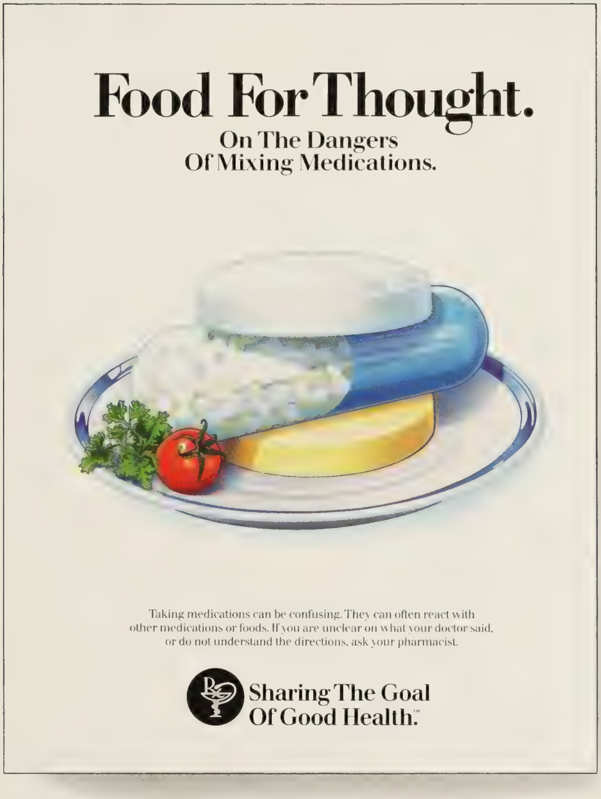

Food For Thought.

On The Dangers
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Taking medications can be confusing. They can often react with other medications or foods. If you are unclear on what your doctor said, or do not understand the directions, ask your pharmacist.

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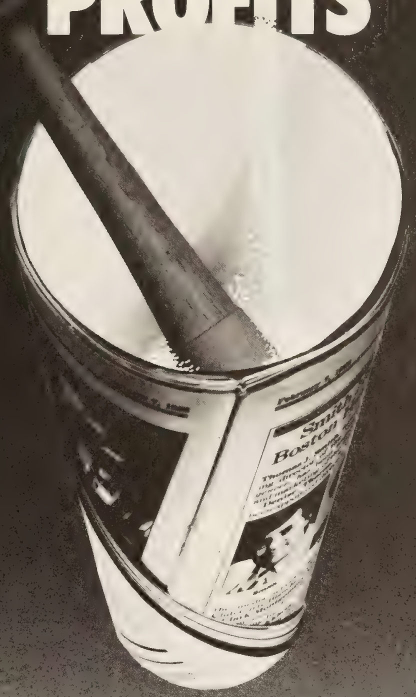

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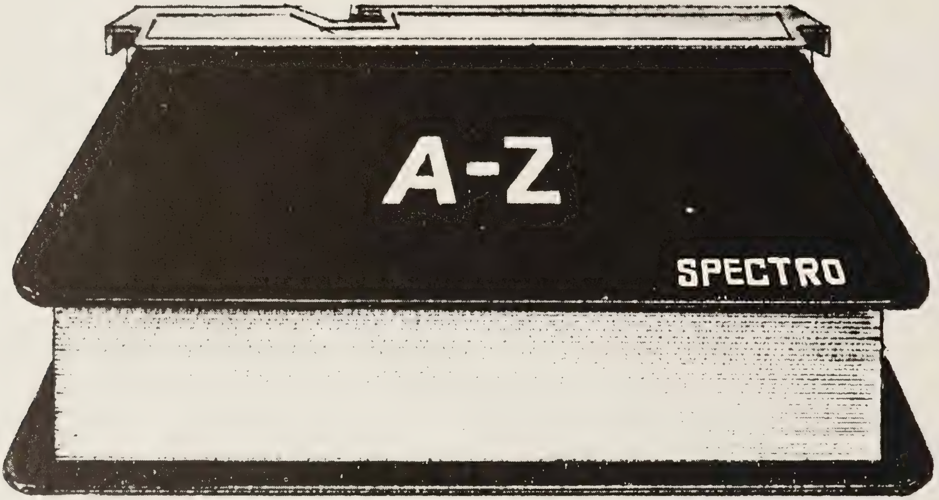

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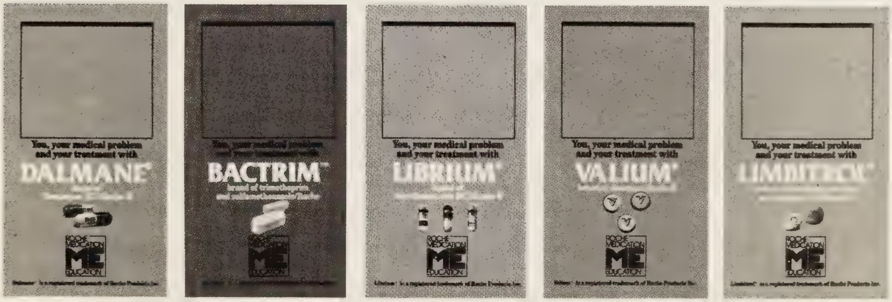
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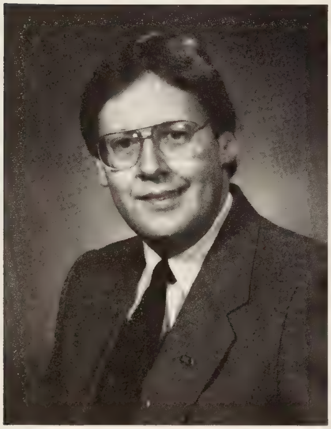

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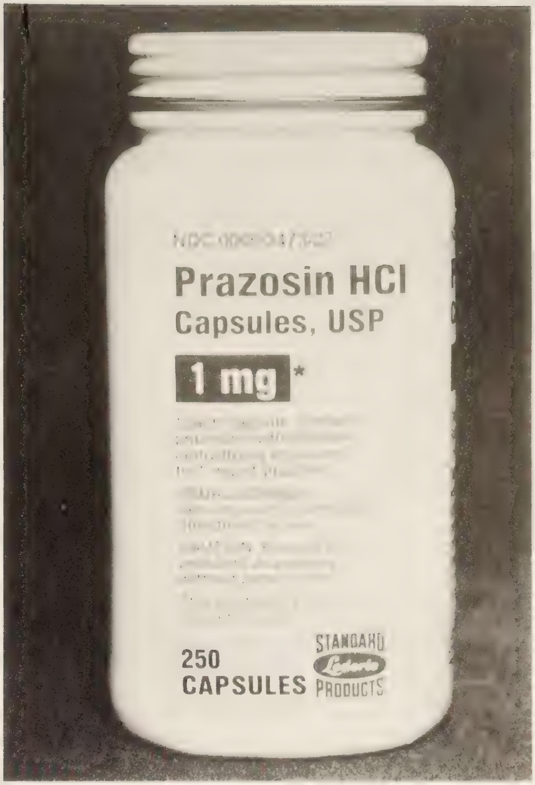
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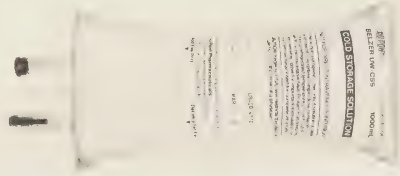
COLD STORAGE SOLUTION

Du Pont Pharmaceuticals has received FDA clearance to market and organ preservation solution for kidneys, livers and pancreases. Called ViaSpan, the solution enables doctors to schedule complicated transplant operations on a non-emergency basis.

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Continuing Education Quiz

The Maryland Pharmacist **JULY, 1989**

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by December, 1989. A continuing education certificate for one contact credit) will be mailed to you within 30 days. Please type or print clearly.

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Is this program used to meet your mandatory CE? ☐ Yes ☐ No

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First Aid Antibiotics

1. Which of the following antibiotics has a spectrum of activity most similar to penicillin, in that it is effective mainly against gram-positive organisms?
   a. Bacitracin
   b. Neomycin
   c. Polymyxin
   d. Tetracycline

2. A pyoderma is most accurately defined as being an infection that produces:
   a. gangrene.
   b. heat.
   c. pus.
   d. redness.

3. All of the following are commercially available as single-entity first aid antibiotic products EXCEPT:
   a. bacitracin.
   b. neomycin.
   c. polymyxin.
   d. tetracycline.

4. Which of the following species of bacteria is LEAST likely to gain entry into the lower layers of the skin and become pathogenic?
   a. Staphylococci
   b. Pseudomonas
   c. Streptococci
   d. Lactobacilli

5. Which of the following antibiotics destroys bacteria via a detergent-like activity?
   a. Bacitracin
   b. Gramicidin
   c. Oxytetracycline
   d. Polymyxin

6. According to its published tentative final monograph, FDA was considering approval of OTC first aid antibiotics in combination with which of the following classes of drugs?
   a. Antifungal agents
   b. Local anesthetics
   c. Keratolytic drugs
   d. Topical antiseptics

7. Which of the following antibiotics is not approved for marketing as an OTC first aid product unless it is in combination with polymyxin?
   a. Bacitracin
   b. Gramicidin
   c. Neomycin
   d. Oxytetracycline

8. The normal pH of the skin inhibits the growth and reproduction of bacteria because it is:
   a. slightly acidic.
   b. neutral.
   c. slightly alkaline.

9. Which of the following antibiotics has the widest spectrum of activity?
   a. Bacitracin
   b. Gramicidin
   c. Neomycin
   d. Polymyxin

10. FDA-approved indications that can appear on the labeling of OTC first aid antibiotics include all of the following EXCEPT:
    a. for decreasing the risk of infection.
    b. to help prevent infection.
    c. for treatment of infection.
    d. to guard against infection.

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AUGUST, 1989 VOL. 65 NO. 8

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Commentary

Are We Missing An Opportunity?

We've all seen the statistics. The elderly represent the fastest growing segment of our population—the consumers of the highest percentage of prescription drugs—the patient group that has the greatest potential for adverse drug reactions. The passage of the Medicare Catastrophic Coverage Act was designed to help alleviate some of the worst health costs for a portion of this population through coverage of prescription drugs, long-term, and home IV care. With the repeal of Medi-Cat a strong possibility, we as pharmacists must focus our attention on an oftimes neglected person . . . the caregiver.

We are all familiar with caregivers. The woman down the street who takes care of her mother and her husband's mother while still managing a household and raising three children. Or the man around the corner who supports his own family as well as an infirm aunt and uncle. Caregivers accept the emotional and financial burdens and responsibilities of providing help to the elderly, oftimes without a strong support system for themselves.

As president, I challenge every Maryland pharmacist to become part of a support system to at least one caregiver they know. At the very least, make copies of the excellent article, "Understanding the Caregiver," and pass it around. Alert people to the Governor's program to assist caregivers. Make a difference to a caregiver.

Nathaniel Futeral, P.D.

President

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Correspondence Course

Advising Consumers on OTC Ibuprofen Products

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, OH

Goals

The goals of this lesson are to:

1. describe the pharmacologic, toxicologic and therapeutic uses for ibuprofen; and
2. discuss specific patient information on methods to maximize efficacy and minimize adverse effects.

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Objectives

At the conclusion of this lesson, the participant will be able to:

1. demonstrate an understanding of the pharmacologic and toxicologic mechanisms of OTC ibuprofen products;
2. identify specific therapeutic uses and official indications for OTC ibuprofen;
3. select specific warnings and precautions associated with ibuprofen; and
4. choose from a list, specific points for advising consumers on the correct use of OTC ibuprofen products.

When ibuprofen products were transferred to the American OTC marketplace in 1984, it marked the first new nonprescription analgesic/antipyretic in nearly three decades. Ibuprofen was approved for OTC marketing based on its proven clinical efficacy, and relative lack of serious toxicity in overdose. While ibuprofen is similar to aspirin in many respects, it also differs from it.

This lesson discusses OTC uses and safety of ibuprofen. Important information for counseling consumers is also presented.

Mechanism of Action

The mechanism of action of ibuprofen is similar to aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs). These drugs inhibit the cyclo-oxygenase enzyme system that metabolizes arachidonic acid to its endoperoxide intermediate product.

Prostaglandins synthesized from the normal arachidonic acid reactions mediate a wide variety of physiological effects. Actions that are pertinent to this discussion include: production of inflammation, sensitization of pain receptors, stimulation of uterine contraction, and temperature regulation.

Some prostaglandins induce pain partially by causing inflammation and partially by sensitizing efferent nerve endings to the action of pain-producing chemicals (e.g., serotonin, bradykinin, and histamine). Prostaglandin-induced pain is long-lasting and accompanied by tenderness and increased painful response to normally nonpainful stimuli.

Pharmacology of Ibuprofen

Ibuprofen is rapidly absorbed after ingestion, reaching plasma peak concentration in 1 to 2 hours. Its biological half-life is 2 to 2.5 hours, so it does not accumulate in the body to a great extent.

Food slows, but does not affect total absorption. If ibuprofen upsets the stomach, it may be taken with food, preferably immediately before meals. If stomach upset continues, acetaminophen may be a more appropriate agent for self-medication in that individual.

Ibuprofen is extensively and firmly bound to plasma protein. However, a single 200 mg dose occupies only a small portion of available protein binding sites, and causes no significant therapeutic problems related to drug interactions. Neither does the 400 mg dosage.

Ibuprofen is metabolized in the liver; metabolites are rapidly and completely excreted in the urine. The rapid metabolism and excretion rates partially explain its high safety profile.

Self Medication with Ibuprofen

Ibuprofen is available in products that are sold OTC and others that have prescription-only status. The reason for two classifications relates to the drug's labeled indications and dosage strengths.

FDA has determined that the 200 mg dosage form is safe for self-medication of pain and conditions listed in Table 1, and for reducing fever. Higher dosage units and treatment of rheumatoid arthritis require professional supervision.

Commercially available OTC ibuprofen dosage forms are listed in Table 2.

For self-medication, ibuprofen is indicated for treatment of a variety of aches, pains and fever in persons 12 years and older. Studies to show safety in children under 12 years have not yet been conducted.

While it is effective for these indications in low doses, higher doses are needed to achieve prolonged anti-inflammatory action. Ibuprofen's analgesic/antipyretic dose range is 200 mg every four to six hours while symptoms persist. If there is no response to 200 mg, 400 mg may be taken, but not to exceed 1200 mg in 24 hours.

Table 2

Representative OTC Ibuprofen Products

Trade Name	Manufacturer
Aches-N-Pains	Lederle
Advil	Whitehall
Haltran	Upjohn
Ibuprofen	Thompson
Medipren	McNeil Consumer
Midol-200	Glenbrook
Nuprin	Bristol-Myers
Pamprin-IB	Chattem
Trendar	Whitehall

Types of Pain Relieved by Ibuprofen in OTC Doses

Dental Pain. A number of studies have compared ibuprofen to aspirin in relieving dental pain. They suggest that ibuprofen, 200 to 400 mg, as compared to aspirin, 325 to 650 mg, is more effective, and exerts a more prolonged relief of dental pain than aspirin at either dose.

Dysmenorrhea. Dysmenorrhea (menstrual cramps) is the most common of all gynecological disorders, reportedly occurring in over one-half of all menstruating women. It causes the greatest loss of work and school days by women.

Dysmenorrhea is primarily caused by the release of prostaglandins (specifically PGE_2 and PGF_{2a}) which stimulate uterine contractions. The actual pain results from oxygen deprivation (ischemia) following decreased blood flow through constricted uterine tissues.

Table 1

Approved Indications for Ibuprofen

OTC Indications

Temporary relief of minor aches and pains associated with:
- the common cold
- headache
- toothache
- muscular aches
- backache
- menstrual cramps
- arthritis

Prescription Indications

Relief of signs and symptoms of rheumatoid arthritis and osteoarthritis, including acute flares, and in their long-term management

Relief of mild to moderate pain

Treatment of primary dysmenorrhea

In a series of double-blind, crossover trials comparing ibuprofen with aspirin, moderate to complete pain relief was reported in 21 to 30 percent of subjects taking aspirin. Over 80 percent of the women experienced relief of discomfort with ibuprofen.

Minor Aches and Pains of Osteoarthritis. Ibuprofen has been the most frequently prescribed drug for pain and inflammation associated with arthritis since its introduction as a prescription drug in 1976. When temporary minor discomfort is present, 200 to 400 mg doses can provide effective pain relief from osteoarthritis. Higher doses are needed to relieve inflammation and subsequent pain of rheumatoid arthritis.

How Does Ibuprofen Compare To Other OTC Analgesics?

Trying to compare the effectiveness of various analgesics in treating pain is difficult. When one considers patient variability, investigator bias (whether obvious or suppressed), the subjective nature of pain (i.e., trying to explain pain to another person so that the person can understand and feel the same experience), and the fact that there is no scientific instrument that can objectively measure pain, then this is understandable.

While studies that have been undertaken to compare pain alleviating effects of the various analgesics have not always been similar in design or outcome, it does appear that 200 mg of ibuprofen is equal to 650 mg of either aspirin or acetaminophen in most people. Ibuprofen in 400 mg doses appears to be more effective than 650 mg of the other two agents, and it shows evidence of having a longer duration of action.

Dysmenorrhea probably presents the best case for ibuprofen superiority over the other two OTC analgesics. This condition is brought on by onset of menstrual sloughing, leading to backache and headache, diarrhea and vomiting, and uterine contractions.

It has been demonstrated that the 400 mg ibuprofen dose is better in alleviating symptoms of dysmenorrhea than either acetaminophen or aspirin in 650 mg doses. The recommended regimen for ibuprofen for

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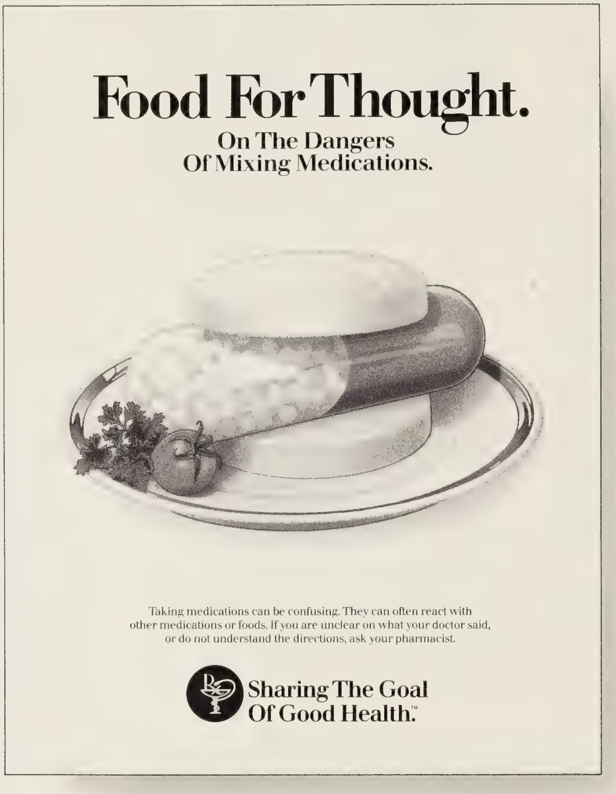

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treating symptoms of dysmenorrhea is 200 to 400 mg four times a day for 2 to 3 days, not to exceed 1200 mg/day.

The theory for superiority of ibuprofen in treating dysmenorrhea is that it has greater selectivity (at OTC doses) in inhibiting prostaglandins, which are produced in excessive amounts when the endometrial accumulations (produced to accept and nourish the fertilized egg) are sloughed off at the beginning of menses. It is felt that overproduction of these prostaglandins leads to local uterine problems and systemic (CNS and GI tract) symptoms.

For fever, there is no evidence that any of the three agents is better than the other two for adults, and ibuprofen is not officially approved for use in children under 12. Since acetaminophen is available in liquid dosage forms, it could be the agent of choice for fever in children.

Toxicity

Safety issues are paramount regarding OTC use of any drug. In order for a prescription drug to be shifted to OTC status, it must possess a high safety factor under widespread use without medical supervision.

Overall, ibuprofen has a low toxicity potential, and superb safety record. Most patients who have overdosed with ibuprofen experienced little more than mild symptoms. When comparing it to aspirin with its side effects, or acetaminophen with its toxicity/death ratio, ibuprofen is clearly a minimally toxic drug.

Ibuprofen has been one of the leading prescription drugs in the U.S. It is used by over seven million Americans annually. During the first 10 years of availability in the U.S., over 103 million prescriptions were filled. Worldwide, more than 19 billion doses have reportedly been taken.

NSAIDs, including ibuprofen, inhibit the renal effects of prostaglandins. They also reduce glomerular filtration rate and renal blood flow. Otherwise healthy persons will not be adversely affected. However, those with pre-existing renal pathology may develop symptoms including the nephrotic syndrome, edema and acute renal failure. These disappear quickly upon discontinuation of therapy.

The hematologic effects of ibuprofen are reported to be similar to but less than those caused by aspirin. Ibuprofen can inhibit platelet aggregation. This effect is quickly terminated once the drug is cleared from the body. The reaction rarely causes clinical problems. On the other hand, ibuprofen does not have a therapeutic indication for platelet aggregation inhibition anticoagulant use. In those patients in whom inhibition of platelet aggregation is not desired, acetaminophen would be safer than either ibuprofen or aspirin, since it has not shown this activity.

Gastric irritation, a commonly encountered problem with aspirin, has also been reported with ibuprofen. However, it is less severe and occurs less frequently than with aspirin. It can cause blood loss in feces and, therefore, should not be used prior to a fecal occult blood test.

Cross-Sensitivity to Aspirin. It has been suggested that there is a 90 percent frequency of cross-sensitivity reactions between ibuprofen and aspirin. Since patients hypersensitive to aspirin can also be allergic to ibuprofen, a warning against self-medication for patients with aspirin sensitivity appears in the labeling of OTC ibuprofen products (Table 3).

Safety During Pregnancy. There is no evidence that ibuprofen is teratogenic in humans. The drug does not enter breast milk. In fact, the American Academy of Pediatrics has recommended that ibuprofen can be safely administered to mothers who are breast-feeding.

Nonetheless, labeling of OTC ibuprofen products warns against its use by pregnant women. This warning is based on the fact that there are no data which establish that the drug is safe for women who are self-medicating and breast-feeding.

Pregnant women should be specifically advised against taking ibuprofen during the third trimester. There are several reasons for this precaution based on pharmacologic actions of nonsteroidal anti-inflammatory agents as a group, rather than just ibuprofen.

First, inhibitors of cyclo-oxygenase reduce uterine contractions. Delivery may therefore be delayed. Some investigators report that this delay may last two weeks or longer.

Table 3

Warning Statement Required on Label of OTC Ibuprofen Products

"Aspirin sensitive patients should not take this product if they have had a severe allergic reaction to aspirin, e.g., asthma, swelling, shock or hives, because even though this product contains no aspirin or salicylates, cross-reaction may occur in patients allergic to aspirin."

Second, nonsteroidal anti-inflammatory drugs cause ante- and postpartum blood loss, stillbirth, and neonatal hemorrhage. These effects for ibuprofen are not currently known.

NSAIDs drugs can also interfere with fetal cardiovascular functions prior to birth. For example, maintenance of the patent ductus arteriosus is important during fetal life. This is an opening which allows blood to bypass the lungs by shunting it directly from the pulmonary artery to the aorta while the fetus is *in utero*. NSAIDs enhance premature closure of the ductus, thus endangering the life of the fetus.

Poisoning

As stated earlier, ibuprofen is safer than either aspirin or acetaminophen when taken in overdose. Adults and children have ingested overdoses of ibuprofen that resulted in blood levels 25 times greater than therapeutic levels with little or no adverse effects. Similar levels of aspirin or acetaminophen would most likely be associated with serious toxicity.

Drug Interactions

There are no well-documented, significant adverse drug interactions involving ibuprofen in OTC doses. The potential for interactions exists in some patients. For example, the ability of ibuprofen to bind with plasma protein suggests that an interaction with other protein-bound drugs, such as warfarin, could occur. But unlike aspirin, ibuprofen does not affect prothrombin time. Reports of this interaction have not been published. In a study of 50 patients stabilized on warfarin and receiving 600 to 1200 mg of ibuprofen daily, there was no change in warfarin's anticoagulant activity as determined by measurement of clotting factors II, VII and X.

In relatively high doses, ibuprofen does reduce platelet aggregation by inhibiting cyclo-oxygenase. In contrast to aspirin, its effects are reversible within 24 hours after discontinuing the drug.

Opinion is divided on the concurrent use of ibuprofen with oral anticoagulants. One side believes that ibuprofen is the safest NSAID for therapy of arthritic patients who need warfarin. Others argue that since ibuprofen does inhibit platelet aggregation, and it may be irritating to the GI tract, acetaminophen is the agent of choice for self-medication of OTC symptoms in patients taking warfarin.

There is a report of potential interaction with loop-diuretics in patients with congestive heart failure, due to ibuprofen's tendency to retain sodium and water. The result of this interaction is to antagonize diuretic action. Also, it has been stated that ibuprofen can decrease renal excretion of digoxin, thus raising its blood level and toxicity. While definite proof of significance has not been demonstrated, acetaminophen might be a better choice for self-medication in patients with congestive heart failure.

Consumer Advice

Numerous studies have documented that ibuprofen is superior to acetaminophen or aspirin in treating its nonprescription indications — i.e., minor aches and pain. It must be realized that individuals may obtain greater relief from any one or the other of these three agents, but when all results are tallied, ibuprofen shows superior results in the majority of persons.

As with aspirin and acetaminophen, OTC ibuprofen usage should be limited to 10 consecutive days for treating pain, 3 days for reducing fever, and 2 to 3 days for dysmenorrhea. Symptoms that do not respond within these periods may indicate that a more serious condition exists for which physician intervention is needed.

Table 4

Representative Comparison of Ibuprofen With Acetaminophen and Aspirin

Effective For:	Ibuprofen	Acetaminophen	Aspirin
Pain relief	yes	yes	yes
Fever	yes	yes	yes
Headache	yes	yes	yes
Dysmenorrhea	yes	yes	yes
Indicated for children under 12	no	yes	yes*
Available in liquid dosage form	no	yes	no
Least likely to cause GI tract distress	—	+	—
Inhibits prothrombin formation	no	no	yes
Interferes with occult blood in stools test	yes	no	yes
Self medication not recommended during third trimester of pregnancy	yes	—	yes

*Indicated, but not recommended

Ibuprofen's most commonly reported side effects are gastrointestinal-related including nausea, mild heartburn and stomach pain. However, the incidence of these is less than with aspirin. If gastrointestinal symptoms appear, the dose can be taken with milk or a light snack. If symptoms persist, the individual should consult a physician. If symptoms unusual to the condition being treated occur, a physician should be consulted before additional doses are taken.

Consumers should be advised against concurrent ingestion of alcohol with ibuprofen. Alcohol can exacerbate the potential gastric irritation of the analgesic.

Geriatric patients should be counseled when they inquire about self-medication with ibuprofen. It has been reported that as few as 12 percent of elderly patients talk to their physicians about the OTCs they take. Similar figures can be expected for confiding with pharmacists. Thus, there is a chance that a geriatric patient could be taking a prescription NSAID for osteoarthritis or rheumatoid arthritis, and purchase an OTC analgesic without realizing that he or she will be taking a dose of drug greater than the physician intended.

Patients taking ibuprofen by prescription may ask whether they can take one of the OTC products instead of the prescription form. It may be prudent to suggest that as long as their condition requires a physician's supervision (e.g., rheumatoid arthritis), they should first check with him before switching.

If ibuprofen is prescribed to treat conditions for which the OTC products are specifically indicated (e.g., headache/dysmenorrhea) and 200 to 400 mg doses are effective, then the patient can be advised that the OTC products are suitable. But, the patient should discuss this with the physician since periodic office visits may be in their best interest.

Ibuprofen is compared with aspirin and acetaminophen in specific points of advice for consumers purchasing an OTC in Table 4. Pharmacists can use these points when counseling consumers on the OTC products.

Dickinson's Pharmacy

Jim Dickinson

The elderly to the rescue! My next-door neighbor is a 77-year-old woman who lives alone, has no family or other regular visitors, and is crippled by severe arthritis. She also has heart disease.

She represents a "silent majority" among the advanced elderly who may hold—unknown to themselves or to you—the key to pharmacy's future as a clinical profession, and to the rescue of independent practice from mail-order and HMO invasion. Demographic studies—to be confirmed in the next U.S. Census next year, I expect—show that she is being joined by millions of "reinforcements" every year, counting those who are many years younger but who already see themselves in her plight.

There will be a doubling of the over-65 population to 52 million by the year 2,000 (one in six).

To protect my neighbor's anonymity, I'll call her Mrs. Gaunt. She is rarely seen any more on her front porch, even in hot weather, because the pain of moving about doesn't make it worth her while.

Mrs. Gaunt refuses to go into a nursing home; she tried that once, and was back home inside of three weeks. She has enough to pay for home care visits, but frankly her personality may be a deterrent to her forming any relationships with such visitors. In any event, the occasional help she has is soon gone. My wife goes in to check on her regularly, but we travel on business so much we're not reliable.

Most people in the neighborhood probably don't know she even exists—how could they?

Yet recently Mrs. Gaunt had a legal problem that brought her to my special attention, as her neighbor. She needed to prove that she might have been mentally compromised by her medications when she signed a document, in order to have it canceled.

I took a note of her drugs, including daily dosage directions, consulted my compendia, and made the following list:

"Meprobamate—Mrs. Gaunt's Rx is 75% of approved maximum daily dosage: common side-effects include drowsiness, dizziness, slurred speech.

"Methocarbamol—50% of maximum dosage: lightheadedness, drowsiness, blurred vision.

"Acetaminophen/codeine—66% of maximum dosage: light-headedness, dizziness, sedation.

"Sinemet—60% of maximum dosage: mental changes, paranoid ideation, dementia.

"Maxzide—25% of maximum dosage: drowsiness, fatigue, dizziness, depression."

This is the kind of service any pharmacist could have done for Mrs. Gaunt—probably much more effectively than my poor effort.

Anyway, Mrs. Gaunt showed the letter to a lawyer, who charged her $100 to cancel the document, and recommended that she see a different doctor.

She showed the letter to a second doctor, who was appalled by the list and promptly stopped all of the analgesic-sedative medications, replacing them with a course of cortisone injections for her arthritis. She's 1,000% better now.

We've all read of nursing home "drug holiday" experiments under controlled conditions, and know that they work.

What Mrs. Gaunt's experience shows is that outside the nursing home, in the neighborhood pharmacy's own backyard, are other opportunities and challenges of the same kind.

All that is needed is a computer software program that links drug, strength and dosing regimen with major adverse effects and interactions. The pharmacist need not visit the patient's home—although that would be preferable—the details can be taken over the phone, and a printout like mine generated and mailed to the patient, or to anyone else the patient requests (i.e., a physician or attorney).

It would be good to have a more sophisticated package that took into account the patient's current weight, known allergies, disease conditions, and other data for a complete profile—and established pharmacy patient profile systems can do that. However, Mrs. Gaunts of this world are presumed not to be already known to the pharmacy in this way—perhaps they are receiving mail-order medications, or are dependent on people bringing them their medicines from whatever pharmacy the visitors use.

(Mrs. Gaunt patronizes a chain drug store, and pays messengers to pick up her prescriptions.)

To be truly effective, a year-round outreach program needs to be maintained in the community—perhaps through the local cable TV system, senior citizen's center, etc. Handled well, such a system could be biggest development in pharmacy.

If any reader would like to know more about this, or offer suggestions, please let me know directly. Write P.O. Box 848, Morgantown, WV 26507-0848, or call me at (304) 291-6690.

This feature is presented on a grant from G.D Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G.D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G.D. Searle & Co.

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Understanding the Caregiver

by
Peter P. Lamy, Ph.D., Sc.D.

> The nicest and only thing you can say to an older American is that "he doesn't look his age" and "doesn't act his age".
>
> Max Lerner, 1957

Nothing much seems to have changed. Or has it? Some 10 or 15 years ago, many of an older person's problems were ascribed to old age. Patients had no specific expectations, health care professionals didn't think much could be done. All this has changed. Patients (and their families) now expect much more (often a pill for each ill) and health care providers approach long-term care much differently and with difficulty. When confronted with vague and non-specific symptoms or problems of dysfunction, it may be hard, if not impossible, to reach a clearcut decision, a decision acceptable to the patient, the caregiver, and the various professionals concerned. Thus, often there may be disagreement. But we have learned that the problems of old age cannot just be managed by a medical approach. Lack of or insufficient medical services or social support services all can lead to the same poor outcome. What matters most is support of the care recipient and the caregiver.

The Care Recipient: The medical conditions of later life tend to be chronic ones that are managed, rather than cured. Elderly also often experience the onset of late-life disabilities and diseases. The problem is more serious if a patient suffers from multiple chronic diseases. Many elderly also suffer from sensory deficits (diminished vision, diminished hearing ability) which further complicate their problems. Thus, they are especially vulnerable to loss of autonomy, including personal, medical and financial decision-making. In short, they move slowly from the category of a medical "consumer" (one who asks for advice, listens to recommendations, makes a decision) to the category of "client" (one who seeks help and accepts it without question).

Often, elderly, when questioned on what will happen when they no longer can or will make a decision, will answer: "my children will take care of me. I assume neither will do anything without consulting the other(s) and reach the best decision for me among themselves."

How optimistic—and, often, how incorrect!

It is most important to determine on a continuous basis whether an elderly patient is competent to make decisions. If the patient has retained that capacity, the next step is to find out whether the patient has delegated that decision-making power, to whom, and to what degree. Even if the patient has delegated that power, the patient may still wish (and should, whenever possible) participate in the decision-making process. Elderly value control of their own lives.

Thus, any help, service and/or advice offered should be designed to help elderly remain as independent as possible, and any service that would foster dependence should be avoided as much as possible. Yet, that may change over time. Many care recipients "age in place". Over time, they may need entirely different commitments by caregivers and assistance with activities they were formerly able to perform.

SeniorReach

The Caregiver: Eighty percent of all "caregiving" is performed by family (mainly spouses, daughters, daughters-in-law), friends and neighbors. This is called the "informal" caregiving network. The rest is offered professionally, by persons who have made care of the elderly their life's work. Eighty percent of that "formal" caregiving is offered by aides.

Caregivers must realize that any effort that supports the patient's independence and does not increase the patient's dependence may be the most appropriate and most helpful in the long run. Help and support should be given in a manner that will permit the care recipient to maintain or attain the highest possible level of functioning and quality of life. Of utmost importance is the fact that all concerned should be very sensitive to the individual's needs to control their own life. Elderly, if they still can get around, even though with help, should be encouraged to participate as family members, neighbors, church-, synagogue-, and club members,

Continued from page 11.

community residents, and friends. Much of the energy of the caregiver is directed to keep the care recipient at home and out of an institution.

There are many different kinds of "informal" caregivers. There are the "long-distance" caregivers, trying to help aged parents living far away, often dealing with little or no information, yet often asked to help. Often, they are frustrated in their efforts, since they appear to "interfere" and "direct" the elder's life.

Then there are the caregiver's "helpers", most often family members or friends not actively participating, but always ready with advice. Difficulties and conflicts often abound. So does anxiety, often in an unnecessary "anticipation" of what might happen in the future. For the primary caregiver, caregiving stress increases with the duration of demands and demands vary as a result of the nature of the diseases and dependency from which the elderly suffer. There is an enormous difference between the need for physical assistance as distinct from the need for constant supervision. While cognitively intact patients are often grateful for their care, care for cognitively impaired patients is more stressful, and most stressful is mental impairment overlaid with disruptive behavior. The burden is always less if the patient has retained a measure of social skills and there is a meaningful relationship between patient, caregiver, and family.

For example, hip fractures mainly result in physical limitations, which may demand physical energy from the caregiver, but a somewhat limited supervisory effort. That may change, if depression, often following a hip fracture, sets in.

Stroke patients may suffer from a range of physical, social, emotional and cognitive disabilities. Yet, patient progress often leads to positive caregiver feelings.

Not so with dementia patients. They suffer primarily from cognitive and behavioral dysfunction and will demand substantial supervision. Caregivers may not expect any appreciation. On the contrary, caregivers of dementia patients report the highest level of chronic fatigue, anger, depression, family conflicts, and loss of friends and hobbies.

It is important to realize that caregivers are not unlimited in what help and services they can provide. Lack of respite and development of their own problems may threaten their ability to help. Interrupted sleep, and incontinence of urine or feces on the patient's part are often "the last straw".

It is also important to realize that it is not always possible to meet all of a care recipient's demands. On the other hand, caregivers must realize that, often, their "best" efforts will not bring "appreciation". Sometimes, indeed, it is necessary, in concert with the primary provider and family members, to do things that care recipients specifically do not want. A careful balance has to be found between the care recipient's wishes and desires and needs, what is reasonable, what is attainable, and what can be done.

To help, we present the *Caregiver's Bill of Rights:*

CAREGIVER'S BILL OF RIGHTS

1. The right to live our own life and retain our dignity and sense of self.
2. The right to choose a plan of caring that accommodates our need and the needs of those we care about.
3. The right to be recognized as a vital and stabilizing source within our families.
4. The right to be free of guilt, anguish, and doubt knowing that the decisions we make are appropriate for our own well being and that of our loved one.
5. The right to be ourselves enough to have confidence that we are doing the best that we are able.
6. With these rights, the disabled and frail elderly will be provided the highest and best care that we are capable of giving, and we may take pride in ourselves.

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Dr. Lamy is Professor and Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly and Assistant Dean, Geriatrics, School of Pharmacy and Professor, Epidemiology and Preventive Medicine, School of Medicine, University of Maryland at Baltimore, MD 21201

Local Pharmacist Receives Recognition Award

Michael Evanko, R.Ph., Manager, Institutional Services, Eakles Pharmacy, 201 Burhaws Boulevard, Hagerstown, Maryland, is a recipient of the MSD Pharmacist Recognition Award. He is a resident of Sharpsburg.

The award was established by Merck Sharp & Dohme (MSD), the U.S. prescription drug division of Merck & Co., to recognize business and civic achievements of pharmacists. Evanko was cited for providing continual pharmacological information to professionals and para-professionals in Western Maryland.

The award will be presented by Hugh Burkhart and John Fanelli, both of Merck Sharp & Dohme.

*Senior*Reach

MEDICATION MANAGEMENT PROGRAM FOR FAMILY CAREGIVERS

Governor William Donald Schaefer recently announced a $100,000 state grant to provide educational programs for the family caregivers of elderly relatives.

Known as the Caregivers Training Program, this service is an innovative approach to the management of medication for the elderly which focuses on that group of family members or friends who care for older relatives at home. In addition to information about the aspects of good caregiving such as nutrition, home safety, and first aid, participants will learn techniques for utilizing community resources available through state and local programs. Pharmacists will provide information about drug dosages, interactions, record keeping, as well as allergies and sensitivities.

"Most older people are receiving care in their own home or in the home of a relative," said Governor Schaefer in announcing the grant. "Regardless of how much you love the person, that type of care is hard work. For the first time, in Maryland, we have a program to help the family member understand how to provide the best possible care for an elderly relative and provides a permanent resource of information to answer caregiver's questions and address their concerns."

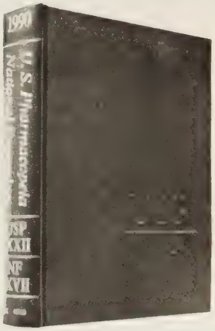
The Maryland Caregivers Program is a five-year project funded by the Governor's Office of Justice Assistance and federal funds allocated through the Drug Free Schools and Communities Act of 1986. The program will be conducted by the Governor's Office of Justice Assistance and staff members of the University of Maryland School of Pharmacy Center For The Study of Pharmacy and Therapeutics For the Elderly.

According to Rosalie A. Abrams, Director of the Maryland Office on Aging, "The family caregiver is a hard working, courageous individual who also suffers from stress, chronic fatigue, depression, and the sense of helplessness that comes from seeing a loved one fall victim to Alzheimers' and similar debilitating conditions. I look forward to the wealth of information and help this program will provide."

The Maryland Caregivers Program will begin with five groups in Baltimore City with priority given to low income family caregivers in the area.

***

FOR FURTHER INFORMATION CONTACT:
Helen Dale 225-1273
Bob Douglas or Louise Hayman 974-2316



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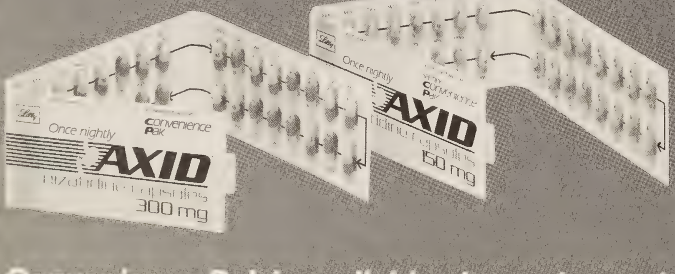

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Brief Summary

Consult the package literature for complete information.

Indications and Usage: Axid is indicated for up to eight weeks for the treatment of active duodenal ulcer In most patients, the ulcer will heal within four weeks

Axid is indicated for maintenance therapy for duodenal ulcer patients at a reduced dosage of 150 mg h.s. after healing of an active duodenal ulcer. The consequences of continuous therapy with Axid for longer than one year are not known.

Contraindication: Axid is contraindicated in patients with known hypersensitivity to the drug and should be used with caution in patients with hypersensitivity to other H_2-receptor antagonists

Precautions: *General* — 1. Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy

2. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects

Laboratory Tests — False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine

Drug Interactions — No interactions have been observed between Axid and theophylline, chlordiazepoxide, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system, therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently

Carcinogenesis, Mutagenesis, Impairment of Fertility — A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice; although hyperplastic nodules of the liver were increased in the high-dose males as compared with placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high-dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement as compared with concurrent controls and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery are not considered evidence of a carcinogenic potential for Axid

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, mouse lymphoma assay, chromosome aberration tests, and a micronucleus test.

In a two-generation, perinatal and postnatal fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy — *Teratogenic Effects* — *Pregnancy Category C* - Oral reproduction studies in rats at doses up to 300 times the human dose and in Dutch Belted rabbits at doses up to 55 times the human dose revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers — Studies conducted in lactating women have shown that <0.1% of the administered oral dose of nizatidine is secreted in human milk in proportion to plasma concentrations. Caution should be exercised when administering nizatidine to a nursing mother.

Pediatric Use — Safety and effectiveness in children have not been established.

Use in Elderly Patients — Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among reported adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs < 0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to determine whether these were caused by nizatidine

Hepatic — Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients and was possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L) and, in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid

Cardiovascular — In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects

CNS — Rare cases of reversible mental confusion have been reported

Endocrine — Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to Axid Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo Rare reports of gynecomastia occurred

Hematologic — Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H_2-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported

Integumental — Sweating and urticaria were reported significantly more frequently in nizatidine- than in placebo-treated patients. Rash and exfoliative dermatitis were also reported.

Hypersensitivity — As with other H_2-receptor antagonists, rare cases of anaphylaxis following administration of nizatidine have been reported. Because cross-sensitivity in this class of compounds has been observed, H_2-receptor antagonists should not be administered to individuals with a history of previous hypersensitivity to these agents. Rare episodes of hypersensitivity reactions (eg, bronchospasm, laryngeal edema, rash, and eosinophilia) have been reported

Other — Hyperuricemia unassociated with gout or nephrolithiasis was reported Eosinophilia, fever, and nausea related to nizatidine administration have been reported

Overdosage: Overdoses of Axid have been reported rarely. The following is provided to serve as a guide should such an overdose be encountered

Signs and Symptoms — There is little clinical experience with overdosage of Axid in humans Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous median lethal doses in the rat and mouse were 301 mg/kg and 232 mg/kg respectively

Treatment — To obtain up-to-date information about the treatment of overdose, a good resource is your certified regional Poison Control Center Telephone numbers of certified poison control centers are listed in the *Physicians' Desk Reference (PDR)*. In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs. and unusual drug kinetics in your patient

If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy Renal dialysis for four to six hours increased plasma clearance

PV 2096 AMP [013089]

Additional information available to the profession on request.

Phobia in the Family: There's No Vacation Without Treatment

"As a youngster, I always felt angry and neglected when my mother couldn't attend the school plays I was in," says Carolyn.

"Not until I was 37 years old did my mother reveal to me that she was phobic about being in large auditoriums with the lights out," Carolyn continues. "She always had plausible excuses for what she avoided. But I sometimes thought she didn't love me enough. I realize now that her phobias humiliated her and made her believe that anyone who knew about them would think she was crazy. But covering them up did more harm to our family than being candid would have done."

An estimated 11 million American adults have phobias in any six-month period. They're the most common of all psychiatric problems.

"While phobias themselves have received increasing media attention, their effects on the families of phobic people have not," says Jerilyn Ross, president of the Phobia Society of America. "The phobia of one individual can have a profound impact on an entire family." The whole pattern of family life may be distorted to accommodate the limitations of the phobic individual. Indeed, those severely hampered by a phobia may have no social life at all.

Family Vacation: No Days Off From Phobias

Even phobic people who confide in their families may wish to conceal their condition from the outside world. As a result, the family may cover up, excuse or even blame the phobic member for the disability and the inconvenience it causes.

Family vacation time, for example, can be a particularly trying period because there's no vacation from phobias. They may prevent people from traveling in planes, trains, buses or cars, from crossing bridges, from entering restaurants or shopping centers or even leaving home at all.

Some phobic people will venture out only in the company of a particularly close friend or family member—the "phobic partner." This relationship places an undue burden on that individual, who may be just a child. It's not unusual, in fact, for a child to serve as caretaker for a parent housebound by a phobia.

Agoraphobia—Most Widely Studied Phobic Disorder

People with agoraphobia—fear of being in places or situations from which escape might be difficult or in which help might not be available if the person is overwhelmed by anxiety or its physical symptoms—are the phobic individuals most likely to seek treatment. Therefore, this condition has been more widely studied than other phobic disorders.

Treatment of agoraphobia often involves some form of behavioral/cognitive therapy. This therapy aims to expose the person—by gradual, preplanned steps—to the feared situations and change thought patterns that contribute to the fear. Medication can sometimes play an important role in this process.

Involving Family, Friends in Therapy Assists Recovery

A recent study compared two groups of married women being treated for agoraphobia. (About 75 percent of people with agoraphobia are women and the majority are married.) Therapy for both groups consisted of 12 weekly group discussion sessions. The first group's sessions included husbands, the second group's did not. Women in both groups were assigned practice tasks between sessions that involved placing themselves in situations they feared. Husbands accompanied wives in the first group on certain of the practice missions.

Two years after treatment, 82 percent of women in the first group were doing well in terms of overcoming their phobias and functioning better in various aspects of their lives. Only 46 percent of the second group achieved as high a level of recovery. Moreover, with spouse involvement women continued to improve over the two-year period, whereas without it there seemed to be some backsliding.

This and other studies were conducted by a group headed by David H. Barlow, Ph.D., professor of psychology at the State University of New York at Albany and co-director of its Center for Stress and Anxiety Disorders. Their findings support the contention that family and friends can assist in recovery, especially when they participate in treatment sessions.

At the sessions, therapists emphasize points such as these:

- Family and friends need to learn that a phobic feeling exceeds mere fear. They must accept the feeling as real, not imaginary, even if it is beyond their own experience.
- They must learn not to ignore anxiety-related behavior or try to overcome it with threats or ridicule.
- Instead, couples must try to communicate more effectively during periods of anxiety. They can use therapy sessions to prepare strategies for handling these rough periods.
- Spouses and friends can learn to serve as confidants as well as coaches—facilitating and motivating practice of difficult tasks.

Continued on page 16. . . .

Ironically, progress in overcoming a phobia sometimes upsets the equilibrium of a marriage or friendship. There are even instances where a husband pressures his wife to return to her dependent, phobic role. But when both participate in the therapeutic process, they can negotiate new roles. Therapy sessions can iron out the misunderstandings that inevitably arise and lay foundations for a healthier, stronger relationship.

"Fortunately, recovery is entirely possible even for phobic people who don't have spouses or close family members to assist them," says Jerilyn Ross. "But when phobic people have support systems—friends and/or family members willing to help them face the situations they fear—these generally give a boost to the process."

Thanks to the existence of skilled therapists, effective treatment options and other resources, today's outlook for most people with phobias is excellent—especially those with supportive family or friends.

Free Booklet

A booklet—"Phobic and Panic Disorders: Getting Help"—that explains phobias and panic disorders and provides a guide to useful treatments is available free. Those wishing copies should send postcards with their names and addresses to:

PHOBIA SOCIETY OF AMERICA
Booklet
P.O. Box 42514
Washington, DC 20015-0514

Wives With Agoraphobia: Recovery Rate Increases When Husbands Participate in Therapy

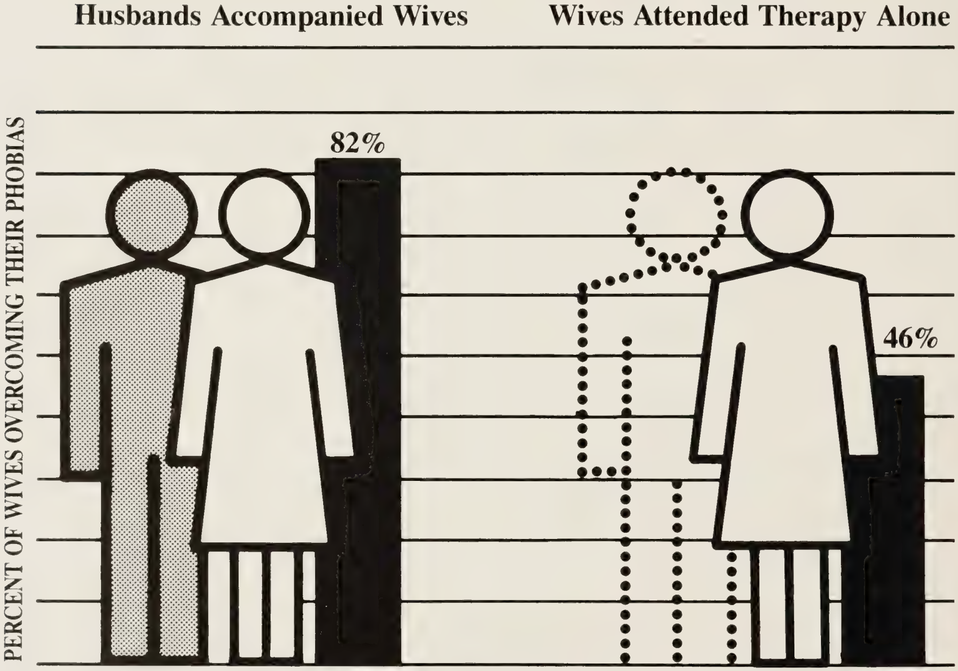

ILLUSTRATION — PHOBIA SOCIETY OF AMERICA

A recent study compared two groups of married women being treated for agoraphobia—a phobia that can be severe enough to make some people housebound. Two years after treatment, 82 percent of those whose husbands had participated in therapy sessions with them were doing well in terms of overcoming their phobias. The same was true of only 46 percent of women who attended therapy alone. (From J. A. Cerny, D. H. Barlow, et al., "Couples Treatment of Agoraphobia: A Two-Year Follow-Up," Behavior Therapy, Vol. 18, 1987, pp. 401-415.)

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3. ARE YOUR HEALTH AND BEAUTY AIDS PRICES COMPETITIVE?
4. IF SO, ARE YOU TELLING YOUR CUSTOMERS?
5. HAS INCREASED THIRD PARTY PRESCRIPTIONS AND COMPETITION AFFECTED YOUR PRESCRIPTION DEPARTMENT PROFIT?
6. ARE YOU TIRED AND CONFUSED FROM SEARCHING FOR THE BEST SOURCE OF SUPPLY, AT THE BEST PRICE, TO FILL YOUR O.T.C. AND PHARMACEUTICAL NEEDS?
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SALES MANAGER

Message from the University of Maryland School of Pharmacy

David A. Knapp, PhD, Acting Dean

The Maryland Pharmacists Association and the University of Maryland School of Pharmacy hold many shared goals, prime among them being the firm desire that pharmacy in Maryland continue to be a strong, effective profession in order to meet the health care needs of the community. It is important that we pause from time to time to reflect on the importance of the partnership between the MPhA, which represents the present realities of pharmacy, and the School, which, as it prepares dozens of new pharmacists each year, represents its future.

Even though this is still the summer of '89, the School of Pharmacy is beginning to look to the year 1991. 1991 will be the 150th anniversary of the founding of the Maryland College of Pharmacy, the predecessor to the modern School of Pharmacy. We have begun to plan a year-long effort to focus attention not only on the School of Pharmacy, but also on the contributions of pharmacy to the state of Maryland. We will soon be asking many of you to help us prepare for this celebration and hope that you will help to make this anniversary a meaningful one.

The pending arrival of our 150th year is also a time for introspection by our faculty. We have begun a review of our goals and directions in light of the many changes within pharmacy, government and society. While by no means complete, I want to share with you some of the areas we are reviewing.

Professional Educational Programs

- Our basic entry-level professional programs are the prime reason for our existence. We are mandated to prepare a steady supply of highly-qualified women and men prepared to begin to practice pharmacy. (Note that I said "begin to practice. . . ." I fear we will never be able to provide you with graduates with a built-in twenty years of experience!)

We constantly review the curriculum and fine tune our programs, but we will take a new look in the near future at the overall structure of our professional programs to assure that we are doing the best possible job of not only educating pharmacists for today's needs but also for tomorrow's challenges.

- The Professional Experience Program, which is led by Marvin Oed, is perhaps the most visible evidence of the continuing partnership between the School and the pharmacists of the state. The first such program in the country, PEP continues to demonstrate that a well-structured professionally-oriented practice experience, as part of a modern curriculum, is the best way to provide a meaningful transition between the classroom and the pharmacy for young pharmacists. Thank you for your help in making the PEP program a continuing success.
- The School also has a responsibility to meet the needs of specialty areas within pharmacy; thus we offer several specialty professional programs. These include the doctor of pharmacy program and the masters program in institutional pharmacy. In recent months, the University of Baltimore has received full accreditation for its MBA program, and we are entering into some preliminary discussions about a possible joint pharmacy—MBA program.
- The School has a stake in life-long learning, as do you. With the advent of mandatory continuing education in the state, so does the Board of Pharmacy! While the School is investigating ways of making curricular-based certificate programs available, we wish to reaffirm our commitment to the Maryland Continuing Education Council. This group, made up of representatives from MPhA, MSHP and the School, is the logical focus for continuing education efforts in the state and deserves your continuing support. There is a great temptation to accept the invitation of well-funded industry sponsors to put on canned CE programs. The Council serves an important role as a filter for such invitations, and to assure quality in all CE programs.

The School is helping the Council to prepare for the coming year by sponsoring a meeting next month that will involve a number of carefully selected consultants. MPhA Vice-President Ilene Zuckerman is organizing the program and is to be commended for taking the lead for your association in this important area.

Graduate Studies and Research

The School has a responsibility that transcends state borders related to producing pharmaceutical scientists for industry, government and education. Our graduate programs in the pharmaceutical sciences enroll about 60 individuals who learn research skills at the side of their faculty mentors. The research efforts of the School have grown dramatically in the last few years. As measured by external research support, which is earned in competition with scientists nationally, our research effort has grown from under a million dollars annually two years ago to $2.2 million through the first three quarters of this year.

Although biomedical laboratory research is an important component of the School's research program, it is not the only area of study. Our faculty are involved in a variety of clinical and practice oriented-studies, including an evaluation of the computer conferencing system many of you are participating in, the Value-Added Pharmacy Services study, and the congressionally-mandated study of mail order pharmacy in the Medicare Catastrophic Coverage Act. This research is not only valuable for its own sake, but also for its energizing effect on the faculty, since it keeps them current and improves their teaching efforts.

Service Programs

The School has always recognized its responsibility to the citizens of the community through its extensive service programs:

- Dr. Peter Lamy's Center for the Study of Pharmacy and Therapeutics in the Elderly and its related caregiver program.
- Tony Tommasello's drug abuse education programs.
- The Maryland Poison Center, directed by Gary Oderda and his dedicated 24-hour staff of pharmacists.

Each of these programs is growing and seeking new ways to improve their contributions to pharmacy and to the community.

Liaison with the Profession

As an academic center devoted to free inquiry and the advancement of the profession of pharmacy, the School is a resource for the profession. We need to continue to expand the partnership with pharmacy in the state to advance programs that will improve the health of the public and meet the needs of society.

In Conclusion

From a personal viewpoint, it has been a year of change in the School. The passing of Dean Leavitt and Tom Patrick have left voids that will not soon be filled, if ever.

Dr. Nicolas Zenker will retire at the end of this month after several dedicated decades on our faculty; he has been awarded Emeritus status and will continue to conduct his research with us.

We have two new department chairpersons: Dr. Gerald Rosen, in pharmacology, has come from Duke University; and Dr. Marilyn Speedie has been promoted from within to head our renamed Department of Biomedicinal Chemistry—nee Medicinal Chemistry/Pharmacognosy.

This was the year that Dean Kinnard came back from sabbatical—and was chosen a few months later to head the campus as Acting President while a search for the successor to Dr. Edward Brandt was conducted. That he was chosen for the post is a testament to the regard with which Dean Kinnard is held in the University and the state.

The rhythm of the School goes on, however. We have graduated a class of 80 this past month; we have admitted a class of 100 for next fall. Our programs are growing, our optimism is apparent and our future is bright. We look forward to continuing to work with the pharmacists of Maryland as we enter the last decade of the twentieth century.

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PHARMACY ACHIEVEMENT SCHOLARSHIP UNIVERSITY OF MARYLAND
School of Pharmacy

The University of Maryland School of Pharmacy's Annual Pharmacy Achievement Scholarship represents an exciting challenge to you as a practitioner concerned with the future of our profession. By sponsoring a qualified high school or college student (Maryland Resident) for this tuition-free one-year scholarship, you will:

1) stimulate general community interest in the profession;
2) encourage one outstanding young person of your acquaintance to choose pharmacy as a career;
3) demonstrate to your colleagues an awareness of the need for more and better pharmacy students.

The guidelines are simple. The student that your sponsor must have a satisfactory record of achievement in high school or college, an interest in pharmacy as a career, a cumulative grade point average of 2.75 or equivalent, and PSAT/SAT scores ready for submission. He or she then completes the Student Section of the form enclosed, while you complete the Pharmacist's Section. *You* then *mail both forms*—to be received no later than midnight December 15th—to:

The Pharmacy Achievement Scholarship Committee
University of Maryland—School of Pharmacy
20 North Pine Street
Baltimore, Maryland 21201

That's all there is to it.

The recipient will be selected by representaives of the School of Pharmacy, the Maryland Pharmaceutical Association, the Alumni Association, the Maryland Pharmaceutical Society and the Maryland Society of Hospital Pharmacists. The award (one year's tuition) will be announced at a formal ceremony for all nominees and sponsors at the School of Pharmacy during the Spring term. The recipient will be required to meet established admission requirements for the School of Pharmacy at the time of entry.

For additional forms or further information, call Dr. Grady Dale, Director of Student Affairs, 328-7650/328-6586.

UNIVERSITY OF MARYLAND PHARMACY ACHIEVEMENT SCHOLARSHIP

APPLICATION
(Please type or print)

PHARMACIST'S SECTION

I nominate ______________________ for the School of Pharmacy Annual Pharmacy Achivement Scholarship.

Pharmacist's Name: ______________________

Address: ______________________

Name of Pharmacy: ______________________

College of Pharmacy: __________ Degree ____

Year ______________________

Telephone # ______________________

Indicate below why you feel this student is deserving of this scholarship. Include how you came to know the student and his/her qualities and attributes. Also include your knowledge of his/her extracurricular activities and how the student has demonstrated an interest in pharmacy as a career.

**Note: All writing must be kept within the space provided. No additional information may be attached. To do so may void the application.

Please make sure the student you have nominated has completed all the information on the other side of this application before sending to the Scholarship Committee.

____
Sponsoring Pharmacist's Signature

____
Date

Send completed form to:
Pharmacy Achievement Scholarship Committee
University of Maryland-School of Pharmacy
Baltimore, Maryland 21201

STUDENT SECTION Date of Application ________________

Name: ______________________________ Telephone # ____________________

Address: ____

Permanent Address (if different from above) ________________________

____

List your most recent place(s) of employment (if any):

	Employer	Dates of Employment	Brief Description of Duties
1.			
2.			

Indicate any extracurricular (social or service) activities.**

Briefly, how did you become interested in pharmacy as a career?**

Describe how you came to know the pharmacist nominating you for this scholarship.**

Include transcript of high school grades (college transcript if beyond first year of college). PSAT, SAT and/or ACT scores must be submitted if not included on transcript. NOTE: The awarding of the scholarship does not constitute admission to the School of Pharmacy. The recipient must be a bona full-time student at the University of Maryland School of Pharmacy in order for the scholarship to be activated.

____
Student's Signature

Note: DO NOT WRITE OUTSIDE of the box or attach additional information. To do so may void the application. THIS APPLICATION MUST BE RECEIVED NO LATER THAN DECEMBER 15TH.

1989
Preliminary Lilly Digest Data

TABLE 1
Lilly Digest Preliminary Report—1989

Averages per Pharmacy	1989 (Preliminary Sample) (1,254 Pharmacies)	1987 (Full Sample) (1,806 Pharmacies)	Amount and Percent of Change
	Percent of Sales	Percent of Sales	
Sales			
Prescription	$ 537,821— 70.5%	$ 450,815— 66.5%	+$87,006—19.3%
Other	224,657— 29.5%	227,333— 33.5%	−$ 2,676— 1.2%
Total Sales	$ 762,478—100.0%	$ 678,148—100.0%	+$84,330—12.4%
Cost of goods sold	520,658— 68.3%	460,660— 67.9%	+$59,998—13.0%
Gross margin	$ 241,820— 31.7%	217,488— 32.1%	+$24,332—11.2%
Expenses			
Proprietor's salary	$ 45,452— 6.0%	$ 42,650— 6.3%	+$ 2,802— 6.6%
Employees' wages	$ 71,490— 9.4%	63,588— 9.4%	+$ 7,902—12.4%
Rent	$ 17,715— 2.3%	15,931— 2.4%	+$ 1,784—11.2%
Miscellaneous Operating costs	81,860— 10.7%	72,607— 10.7%	+$ 9,253—12.7%
Total Expenses	$ 216,517— 28.4%	$ 194,776— 28.8%	+$21,741—11.2%
Net profit before taxes	$ 25,303— 3.3%	$ 22,712— 3.3%	+$ 2,591—11.4%
Total income (includes proprietor's salary)	$ 70,755— 9.3%	$ 65,362— 9.6%	+$ 5,393— 8.3%
Inventory at cost			
Prescription	$ 54,367— 10.1%	$ 47,096— 10.4%	+$ 7,271—15.4%
Other	49,425— 22.0%	48,790— 21.5%	+$ 635— 1.3%
Total	$ 103,792— 13.6%	$ 95,886— 14.1%	+$ 7,906— 7.6%
Annual rate of turnover of inventory	5.0 times	4.9 times	
Prescriptions			
New	16,778— 52.2%	18,322— 62.5%	− 1,544— 8.4%
Renewed	15,347— 47.8%	11,011— 37.5%	+ 4,336—39.4%
Total	32,125—100.0%	29,333—100.0%	+ 2,792— 9.5%
Average prescription charge	$ 16.74	$ 15.37	+$ 1.37— 8.9%
Third party prescription	37%	30%	+ 2— 7.0%
Floor area	2,826 sq ft	2,824 sq ft	
and sales per square foot*	$ 269.81	$ 233.02	+$ 36.79—15.8%
Pharmacy hours open	59	60	− 1

* Based on averages of pharmacies that reported all data.

Are Your Taxes Done? Not By A Long Shot!

by
Gerald I. Klein
Consulting Group Associate
Shearson Lehman Hutton
217 E. Redwood St.
21st Floor
Baltimore, Md. 21202

You could almost hear the country heave a collective sigh of relief at midnight April 17. That was the official end of the tax season this year.

For many it signalled the start of a nine-month vacation from worrying about Uncle Sam's hand in their pocket. But for the financially prudent, it meant time to review ways to reduce the tax bite on this year's income.

According to the experts, everything you need to know about minimizing your taxes falls into two categories: maximize your deductions and minimize your taxable income. After that, it gets tricky, but we can break it down into some basic guidelines.

Accelerate or Defer Income and Deductions—In making a decision, you will not only need to project your income and deductions for 1989, but for 1990 too. You may wish to defer income and accelerate deductions if you feel that your 1989 income will be greater than what you think you'll earn in 1990. On the other hand, if you feel that your 1990 income will be greater than what you expect to earn in 1989, you should consider accelerating income and deferring deductions. These strategies may be used to reduce or avoid the impact of having your income taxed at a higher tax bracket.

Take Advantage of All Deductions—The number of deductions available to taxpayers had been seriously reduced by the Tax Reform Act of 1986, making those that remain all the more valuable.

Let's look at medical expenses, for example. If you itemize deductions, only the amount that exceeds 7.5% of your adjusted gross income will be deductible. That means if your adjusted gross is $50,000 your medical expenses over $3,750 would be deductible. If you anticipate incurring significant expenses next year, you may want to postpone elective medical care you planned for 1989 until 1990. Grouping these expenses together will give you a greater chance of being able to benefit from this deduction.

Interest paid on loans is another area you should look at. This year, just 20% of consumer interest (such as credit card or personal loan interest) is deductible; next year that will drop to 10%, and will be eliminated in 1991. Since, in most cases interest on home loans remain 100% deductible, you should consider applying for a home equity loan to pay off your other loans and consolidate your debt. If your loan does not exceed $100,000 this will allow you to convert consumer interest that is mostly nondeductible to interest that is fully deductible.

Don't forget about your IRA. If you're still eligible for an Individual Retirement Account deduction, your contribution will lower your taxable income. If you're not, income earned on your contribution will not be subject to current taxation until the earlier on 70½ or until you withdraw from your current account. And you gain again if you contribute to your IRA early in the year; the power of compounding interest on interest could add more dollars to your retirement pot. Self-employed individuals should also consider establishing or making contributions to a Keogh account.

Minimize Taxes on Your Investments—With proper planning, you can benefit from certain deductions and losses. Currently, you may only deduct up to $3,000 ($1,500 if you are married and are filing separately) in capital losses in a given year. These losses may only be offset by capital gains—excess capital losses are carried over to subsequent tax years. If you anticipate generating excess capital loses during the year, selling securities with already existing gains will allow you to currently benefit from these losses.

Medicare recipients and people over 65 should also be aware of the new tax imposed by the Medicare Catastrophic Coverage Act. This year individuals eligible for Part A Medicare coverage will have to pay a tax surcharge of $22.50 for every $150 of tax liability to the maximum of $800. The maximum premium goes up by $50 every year until 1993 when it stabilized at $1050. Thus, if you reduce your federal tax liability, you will reduce the surcharge.

So if you were thinking about taking a mental vacation from income taxes, think again. Some planning now could save you headaches and dollars in April 1990. Before implementing any of these strategies, be sure to consult your tax advisor.

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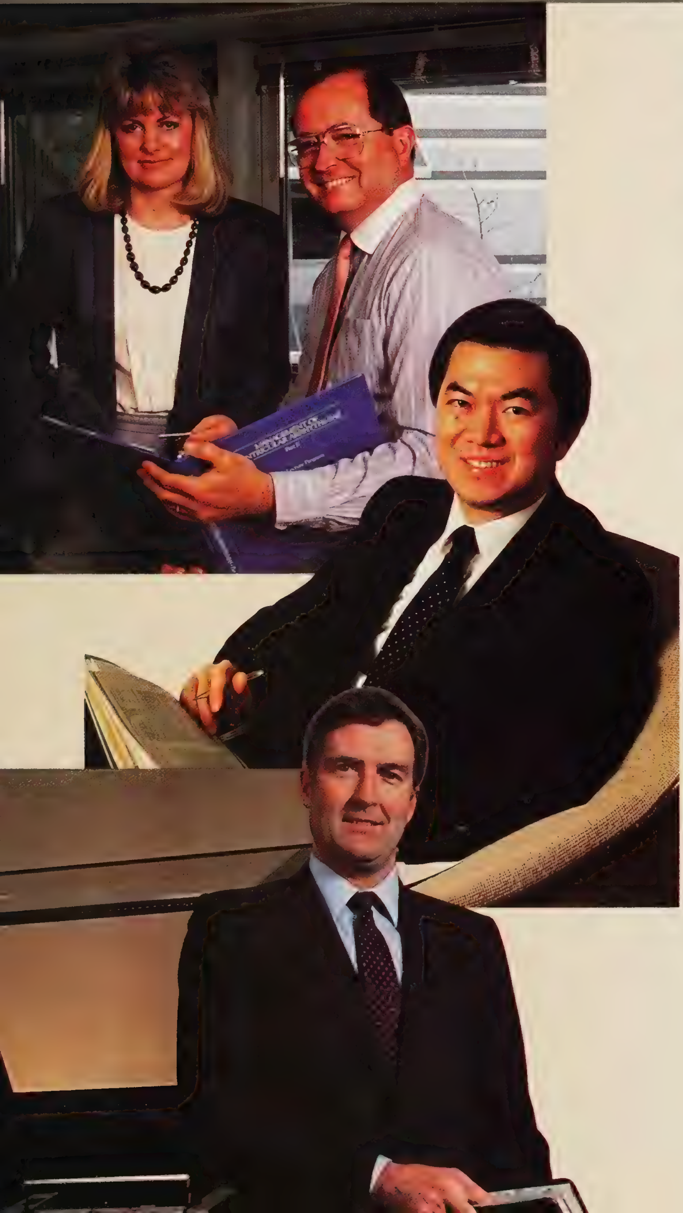

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Led by William Wardell, MD, PhD, Vice President, Medical Director (below, left), the group is made up of physicians and specialists in various medically related fields.

People like Thomas Chin, PharmD, Manager, Medical Information Services (center), Laura McGuire, RN, Assistant Director, Clinical Investigation (above, right), and Kathryn Riccio, Manager, Medical Education and John Elliott, RPh, Manager, Conventions and Scientific Exhibits (above, left).

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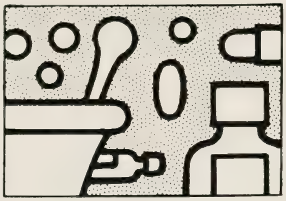
Things You Should Know FOR YOUR GOOD HEALTH



Breaking Through A Misconception Barrier

Epilepsy — millions of Americans have it, yet, it remains one of the most misunderstood medical conditions. Through the years, epilepsy has been mistakenly classified by the uninformed along-side mental retardation, cerebral palsy, or psychiatric illness. At one time epilepsy was considered a contagious disease; it is not. Because this condition has been and continues to be surrounded by misconception, people are reluctant to associate with epileptics.

Epilepsy is a condition in which the usually smooth functioning nervous impulses in the brain are impeded. Although researchers are want for an explanation of the exact cause, it is recognized that an epileptic condition usually results from damaged motor cells in the brain. Electronic brain impulses that try to travel through these damaged cells are forced to find alternate paths which may overload already busy circuits. As a result, people with epilepsy may have a sudden loss or disturbance in consciousness usually associated with a motor function.

Such disturbances, called seizures or convulsions, vary in duration and intensity. In the "classic" grand mal seizure, the victim may lose consciousness and experience muscle stiffening and flexing. During this time — usually two to five minutes — breathing appears difficult, saliva may accumulate in the mouth, and the bladder may empty.

There is no cure for epilepsy, although some people, particularly children, appear to outgrow it.

However, about 80 percent of epileptic seizures can be controlled with medications. Thus, many of those with epilepsy can enjoy a seizure-free life while engaging in most kinds of activities.

What can you do to help a person experiencing a grand mal epileptic seizure?

1. If you or the person with epilepsy senses an impending seizure early enough, you may be able to help the person lie on the ground.
2. Don't try to restrain the person. The seizure must run its course; it can't be stopped once it has begun.
3. Clear the area; particularly, remove hard or dangerous objects so the person experiencing the seizure will not be injured by them.
4. If the person is wearing glasses, remove them.
5. Loosen clothing in the neck and head area.
6. Turn the person on the side to allow saliva to drain from the mouth.
7. Do not place any hard object in the mouth or between the teeth. (It could cause choking or damage to the mouth or teeth.)
8. When the person regains consciousness and the seizure ends, help find a place to rest or become reoriented.

To learn more about epilepsy, ASK YOUR PHARMACIST. It's For Your Good Health.

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*Senior*Reach

No matter what age you are or what shape you're in, there's an exercise for you. In fact, regular exercise can improve your life. Different kinds of exercise can improve your flexibility, strength and the condition of your heart and lungs.

If you haven't been exercising, you'll want to start gradually. Check with your doctor before you begin to exercise. Exercisng to increase your flexibility is a good way to begin. Increased flexibility can relieve minor aches and pains, help prevent lower back pain and may reduce your risk for injuries.

As one gets older, one's muscles may weaken. But regular weight bearing exercise, for example walking, can help overcome the problem. Done regularly, exercise can increase your muscle strength and help you move and feel better.

Brisk walking, bicycling and swimming are examples of aerobic exercises that can improve the condition of your heart and lungs and reduce your risk of heart problems. You need to do them at least three times per week.

Before exercising it's important to warm up by stretching or starting slowly at first. Then get your heart rate up to your target heart rate (see below) for a minimum of 15 to 20 minutes. When finished, reduce the pace of your exercise gradually to get your heart rate and breathing back to normal.

More information on specific physical fitness exercises suitable for older person may be obtained from the Maryland Office On Aging. Call 1-800-AGE-DIAL to request it.

Age	Target Heart Rate
50	102–127 beats per minute
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60	96–120 beats per minute
65	93–116 beats per minute
70	90–113 beats per minute

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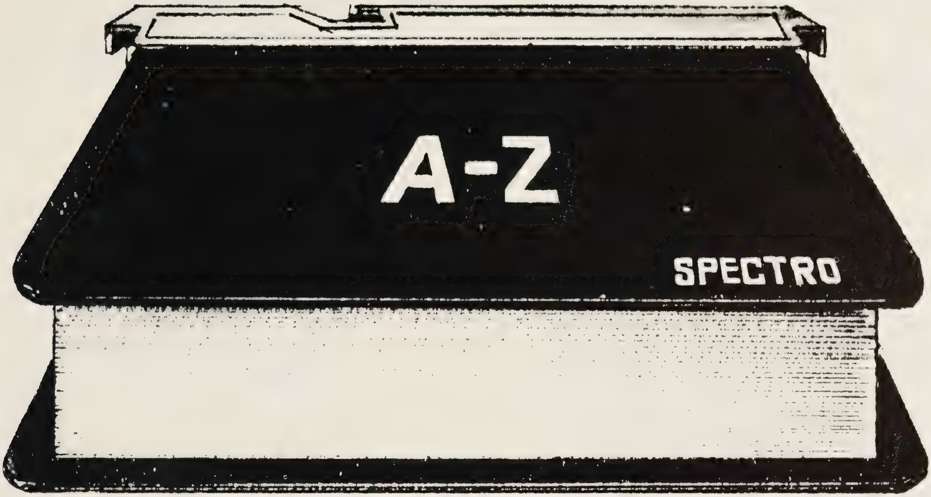

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DRUG PRODUCT QUALITY
Review
A PUBLICATION OF THE USP DRUG PRODUCT
PROBLEM REPORTING PROGRAM

No. 7

USP REQUIREMENTS FOR LIGHT-SENSITIVE PRODUCTS

During the past year, multiple reports of drug product degradation prior to product expiration were received through USP DPPR. As far as the pharmacists submitting the reports were aware, the products had not been exposed to extreme conditions of temperature or humidity. The products were light sensitive. A few examples follow:

Furosemide

Several reports noted a color change in Furosemide Tablets. Discoloration was observed particularly in unit-dose containers. One manufacturer responded, that its opaque carton of 100 blistered tablets provided enough protection from light to allow an expiration date of two years. The firm further stated that there have been no known stability problems when the product was stored in the original package.

Promethazine

The USP DPPR Program has received numerous reports of crystallization and occasional discoloration of Promethazine Hydrochloride Injection even though, in most cases, the injection was packaged in an amber ampul or vial. One firm responded that Promethazine Hydrochloride Injection is extremely light sensitive and forms a crystalline degradation product, 10-methylphenothiazine, upon exposure to light. In this instance, the amber ampuls did not provide sufficient protection from light. The product's labeling warns that the product should not only be protected from light until ready to use, but should be stored in the box as well. The firm concluded that if the Promethazine ampuls are stored in this manner, degradation and resultant crystallization will not occur.

Isoetharine

Many reports regarding the discoloration of Isoetharine Inhalation Solution have been received by the USP DPPR. One manufacturer recommends that the product be stored in the original pouch until the time of use.

• • •

USP Review

Light can affect the stability of many pharmaceutical products. Exposure to ultraviolet and/or visible light can excite electrons of an atom within a given molecule sufficient to either induce the molecule to undergo molecular rearrangement to isomeric molecules, or to break chemical bonds to generate free radicals, which may further undergo reactions to produce new types of compounds. In either case, new chemical entities thus formed are considered to be degradation products. The formulation of these degradation products could lead to loss of potency of the active ingredient in the drug product, crystallization, discoloration, and/or change in the taste or odor.

In some cases, discoloration of a product is actually the result of light degrading the dye used to color the product, rather than a degradation of the active ingredient. Therefore, one cannot assume that a product's potency is affected when discoloration occurs.

The products listed above are only a few examples of the many products that require protection from light. Protection from light, as stated in the USP-NF, can be accomplished by using light-resistant material to make the container (e.g., amber glass), or by applying a light-resistant coating to the container. The container must then meet USP requirements for *Light Transmission* (USP XXI p. 1233). This USP test involves measuring the maximum percentage of light transmission at specific wavelengths. One should not assume that a colored container or film indicates "light-resistance"; use containers and films that meet the requirements of the USP *Light Transmission* test.

A product can also be made light-resistant by using an opaque outer covering, such as an outer box or package. In this case, the label of the container should bear a statement that the drug product must be stored inside the closed container until the contents are used. A container made "light-resistant" by storing in an opaque outer carton meets USP requirements. USP XXI makes it clear that when a product is packaged in a container which is made light-resistant by means of an opaque covering, the covering must remain in place until the contents are to be USED or ADMINISTERED.

Pharmacists should be aware that any USP monograph directing "protect from light" requires packaging the drug product in light-resistant containers not only by the manufacturer, but also by the pharmacist when the drug is dispensed.*

To report drug product problems or for further information, call the USP DPPR Program at 1-800-638-6725.

*Container specifications for dispensing capsules and tablets can be found on pp. 1436–1440 of the USP XXI-NF XVI and pp. IV/1-99, V/1-30 of the 1989 USP DI Volume III, *Approved Drug Products and Legal Requirements*.

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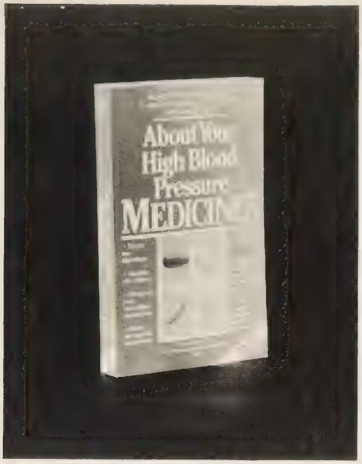
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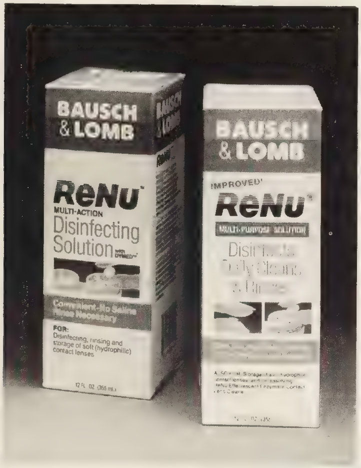
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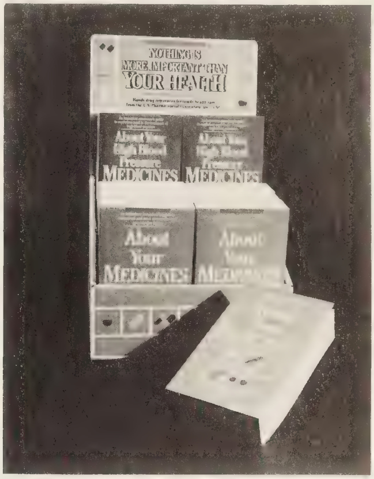
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Continuing Education Quiz

The Maryland Pharmacist August, 1989

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by December 31, 1989. A continuing education certificate for one contact hour (one credit) will be mailed to you within 30 days. Please type or print clearly.

Name ____________________

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Is this program used to meet your mandatory CE? [ ] Yes [ ] No

Did this article achieve its stated objectives? [ ] Yes [ ] No

How long did it take you to complete the program? __________ minutes

Ibuprofen

1. The major reason why ibuprofen 200 mg is OTC while larger dosage strengths require a prescription for purchase is the:
   a. proven toxicity of larger doses.
   b. salt forms used.
   c. release rate of the dosage forms.
   d. labeled indications.

2. Which of the following is LEAST likely to inhibit platelet aggregation?
   a. Acetaminophen
   b. Aspirin
   c. Ibuprofen

3. Ibuprofen is most likely to have an adverse effect on a fetus during the:
   a. first trimester.
   b. second trimester.
   c. third trimester.

4. All of the following statements are true EXCEPT:
   a. although ibuprofen extensively and firmly binds to plasma protein, there is no evidence that it causes significant drug interactions.
   b. ibuprofen accumulates in the body, potentially causing toxicity.
   c. food slows but does not affect total ibuprofen absorption.
   d. ibuprofen is rapidly absorbed after ingestion.

5. Ibuprofen has shown the greatest superiority over the other two analgesics/antipyretics in the treatment of:
   a. osteoporosis.
   b. dysmenorrhea.
   c. fever.
   d. dental pain.

6. The greatest degree of cross-sensitivity and subsequent allergic reactions is reportedly between ibuprofen and:
   a. acetaminophen.
   b. aspirin.
   c. caffeine.
   d. codeine.

7. Ibuprofen inhibits which of the following enzyme systems?
   a. Cyclo-oxygenase
   b. Dopa-decarboxylase
   c. Monoamine oxidase
   d. Xanthine oxidase

8. The enzyme system referred to in question #7 above, metabolizes:
   a. arachidonic acid.
   b. carbonic acid.
   c. folic acid.
   d. lactic acid.

9. All of the following statements are true about dysmenorrhea EXCEPT:
   a. pain results from oxygen deprivation of uterine tissue.
   b. it is caused by release of prostaglandins.
   c. it is reported to be the most common gynecological disorder.
   d. it is brought on by excessive relaxation of uterine muscle.

10. Ibuprofen has shown the LEAST superiority over the other two OTC analgesic/antipyretics in the treatment of:
   a. osteoarthritis.
   b. dysmenorrhea.
   c. fever.
   d. dental pain.

Classifieds

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

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EVERY SUNDAY MORNING at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the pharmacy public relations program, "Your Best Neighbor," the oldest continuous public service show in Baltimore.

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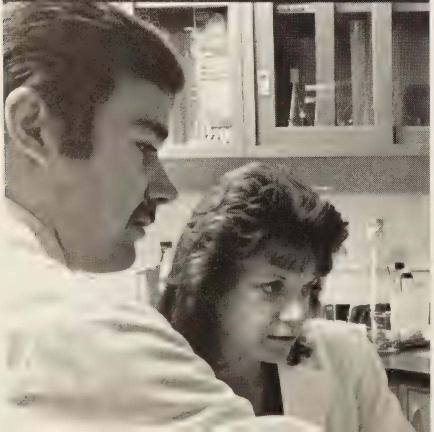

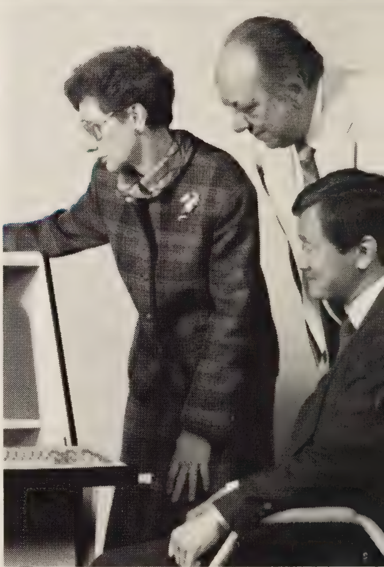

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The Maryland Pharmacist

VOL. 65 SEPTEMBER, 1989 NO. 9

Mysteries of Destructive Molecules

THE MARYLAND PHARMACIST

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SEPTEMBER, 1989 VOL. 65 NO. 9

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A Democratic Republic

Let's talk a little about history. In the very early days of our country, there was great debate about the wisdom of government by the people. The Democrats, led by Thomas Jefferson, believed that all people, regardless of education, the amount of land they owned, or where they came from, must have input into the ways in which the nation should be run. The Federalists held the position that only the rich or landed gentry had sufficient education, background, and time to properly lead a nation.

The result? A combination of democratic input by all people in elections and referendums and a republican representation through a Congress and Senate.

The Maryland Pharmacists Association is built upon these same principles in its Constitution and Bylaws. All members have input into the policy making decisions of the MPhA through representatives in the House of Delegates and elected officials and trustees. In addition, there is much opportunity to affect MPhA's future through the activities of its many committees.

One of my personal goals during my year as president has been to formalize and strengthen the committee process. I have appointed excellent representatives from the membership to chair and/or serve on our committees. Each committee makes written recommendations for implementation of new programs, policies, legislation and services to the Board of Trustees. The Board, as the elected "Congress" of MPhA, then debates and votes on these recommendations.

You must be an integral part of this process. At a minimum, exercise your rights as a member through voting for elected officials when ballots are mailed in March. Attend the House of Delegates meetings at the Mid-Year in February and again at the Convention in June. Volunteer to serve on a policy committee. Better yet, submit your name to run for an elected position within MPhA.

The more involved each member becomes, the more democratic MPhA becomes.

Sincerely,

Nathaniel Futeral, P.D.

MPhA President

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Anabolic Steroids in Competitive Sports

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, OH

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

Goals

The goals of this lesson are to discuss the current status of anabolic steroid use, and describe their pharmacologic and potential toxicologic effects.

Objectives

At the conclusion of this lesson, the participant should be able to:

1. choose terms relevant to understanding pharmacologic and toxicologic aspects of anabolic steroids;
2. select the mechanism of action of anabolic steroids, and identify their legitimate medical uses;
3. demonstrate an understanding of precautions, warnings, and adverse reactions associated with anabolic steroids;
4. determine illicit applications of anabolic steroids; and
5. exhibit knowledge of different ways pharmacists can become involved in educating the public about these drugs.

Gossel

Wuest

in the service of pharmacy

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Some will die outright from complications! Others will survive, but will be plagued with life-long drug-induced adversity. Both scenarios can result from illicit anabolic steroid use which has been described as the greatest drug abuse problem in sports today.

While some of these drugs are obtained from sympathetic, uninformed, or unethical physicians, pharmacists, or veterinarians, others are obtained through unapproved sources.

All told, the illicit anabolic steroid market is conservatively estimated to be a $100 million a year black market enterprise. Approximately one million Americans reportedly use or have used these drugs.

This article discusses anabolic steroids, concentrating on their pharmacologic and toxicologic actions. It summarizes their legitimate medical uses, and discusses the rationale for illicit use in body building programs and other athletic endeavors. It provides information for pharmacists to aid their own understanding, and to answer consumers' questions about anabolic steroids.

Background

Historical records indicate that the medical problem of steroid abuse began with Russian athletes competing in international sports competitions in the early 1950s. Some women athletes were so masculine appearing, following androgenic steroid use, that they required chromosomal tests to confirm their true gender.

American medical research played a role by manipulating the molecular structure of testosterone to develop steroid drugs that more specifically stimulated the metabolic production of protein. These were intended to cause the muscles to enlarge, without producing unpleasant androgenic side effects. The new generation of drugs was named "anabolic steroids" and their legitimate use was to promote weight gain in debilitated patients.

Terminology. Three basic terms must be understood in order to comprehend the overall topic of anabolic steroid abuse. **Anabolic** (i.e., anabolism) refers to the process by which a living organism converts simple substances into more complex forms. **Androgen** defines the natural male sex hormone, testosterone.

Anabolic steroids (anabolics) are synthetic derivatives of testosterone. They possess all the actions of testosterone, but have been chemically engineered to have high-anabolic-to-low androgenic activity. However, the fact that anabolic steroids do possess androgenic action may be one of the most misunderstood concepts by the laity about these drugs. This is where the confusion generally starts, i.e., all anabolic steroids possess significant testosterone-like action. Any of these drugs in appropriate doses can effectively support the physiologic masculinizing functions of castrated or androgen-deficient males.

Representative anabolic steroid drug products are summarized in Table 1. Various veterinary products which are also used illegitimately by people for their anabolic activity could be added to this list.

FDA also reports that there are numerous counterfeit versions of the legitimate drugs, many of them manufactured without regard to controls, in underground laboratories, or smuggled into the country from foreign sources. A large share comes from Europe. Mexico continues to be a major exporter. Some injectable products labeled as anabolic steroids have been found to contain only water, while counterfeit tablets have been analyzed with no active ingredient.

Legitimate Uses

Anabolic steroids have legitimate medical uses. FDA-approved indications are discussed below. All legitimate anabolic steroid products are approved for one or more of these uses.

Anemia. Anemia resulting from use of antineoplastic drugs and potent antibiotics that cause a decrease in bone marrow function is a legitimate indication. Because anabolic steroids stimulate bone marrow (e.g., stimulate erythropoieses), this probably explains their beneficial action on increasing red blood cell (erythrocyte) count.

Offsetting Corticosteroid-induced Catabolism. Chronic therapy with corticosteroid drugs can cause a catabolic (breaking down, opposite effect of anabolic) action on the body's tissues. Individuals on chronic corticosteroid therapy often gain weight from fluid retention, but lose tissue mass. Anabolic steroids administered concomitantly with corticosteroids in selected individuals may reduce tissue degradation. On the other hand, anabolics do not inhibit the anti-inflammatory action of corticosteroids.

Hereditary Angioedema. This rare congenital form of urticaria (hives) can result in extreme pain. In its severe form, it can lead to inflammation of the trachea with suffocation.

Osteoporosis. Anabolics are not indicated for treatment of osteoporosis characterized by poor calcium uptake into bone or excessive calcium loss from bone. They do not stimulate remineralization of bone. Rather, they promote development of the protein matrix within bone, and therefore, are indicated when this is the cause of osteoporosis.

Weight Gain. Candidates for anabolic steroids are usually undernourished and underweight following chronic disease or nutritional deficiency. They may ingest insufficient calories, or those that they do ingest are inefficiently utilized by their tissues. Anabolics stimulate the appetite, and add mass to the body's tissues as will be explained later.

TABLE 1

Representative Anabolic Steroid Products

Generic Name	Trade Name	Manufacturer(s)	Anabolic: Androgenic Ratio*
Oxandrolone	Anavar	Searle	13:1
Oxymetholone	Androl-50	Syntex	3:1
Nandrolone phenpropionate	Anabolin Androlone Durabolin Hybolin Improved	Alto Keene Organon Hyrex	5:1
Nandrolone decanoate	Anabolin LA Androlone-D Deca-Durabolin Decolone-50 Hybolin Decanoate Nandrobolic L. A. Neo-Durabolic	Alto Keene Organon Kay Hyrex Forest Pharm Hauck	5:1
Stanozolol	Winstrol	Winthrop-Breon	6:1
Testosterone	various	various	1:1

*Approximate ratios, based on testosterone (1:1). The higher the ratio (i.e., 13:1), the lower the androgenic effects.

Pharmacology

The precise pharmacologic mechanism of anabolic steroids and their actions are not thoroughly understood. All cells of the body are believed to contain cytoplasmic protein receptors that are responsive to testosterone. The hormone-receptor complex acts upon the nucleus to stimulate increased synthesis of RNA polymerase and other enzymes. Anabolic steroids also bind to these receptors and, in turn, stimulate cells to respond similarly.

The precise biochemical function of RNA polymerase is complex. Basically, it promotes protein anabolism by regulating assembly of simple amino acids into their proper sequence to form more complex proteins.

For anabolic steroids to be effective in building protein, individuals must concurrently ingest a diet rich in calories and protein. Forced intake of dietary protein is needed to supply the amino acids the body needs to manufacture its own protein. The body catabolizes ingested protein into constituent amino acids, and then reassembles them by the process discussed above, into new protein that will be incorporated into human muscle mass and other tissues.

Anabolic Steroids in Sports

Many athletes, even if they have never used the drugs, believe that anabolic steroids increase muscle mass and physical strength. Illicit anabolic drug use is not limited to adult male athletes. Junior high and high school students and women also use them.

A 1985 report summarized the results of 25 separate investigations of anabolic steroid efficacy. Each study followed established scientific protocols. Their results described a wide variety of outcomes, some negative, others positive. The review concluded that the disparity of literature

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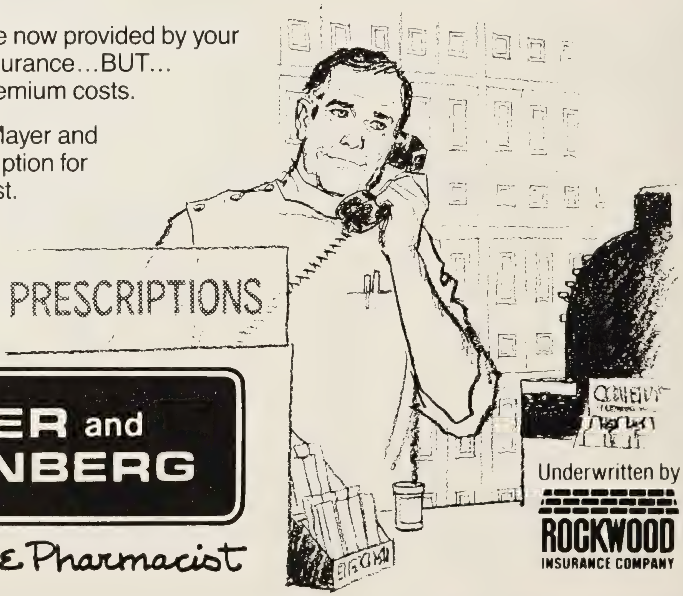

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results was due to the investigators evaluating different points. They therefore followed different, though sound, investigative protocols. When all the data were summarized, the evidence strongly confirmed anabolic drug action to increase athletic performance and muscle strength.

The review article also demonstrated that for consistent improvement in muscle mass to occur, two criteria must be met. First, individuals must consume a high caloric diet. Second, strenuous exercise must be initiated before drug therapy begins and be continued throughout the course of drug administration. In other words, casual drug administration and anything less than strenuous exercise results in little or no positive response.

There are numerous reasons reported why athletes choose to use anabolic steroids. These can be grouped into the following categories.

First, they believe that anabolics increase muscle mass and strength. These individuals contend that they compete better in sports-related activities. Even men and women who are disinterested in sports believe the drugs make them look more physically and sexually attractive.

Second, athletes contend that the drugs decrease muscle recovery time following exercises. So within a short period of time, more exercise can be engaged in, resulting in greater muscle mass development. Athletes also argue that anabolics decrease muscle healing time following injury.

And finally, athletes believe the drugs enhance their aggressiveness and competitiveness in contact sports. Laboratory animal studies support enhanced aggression. Clinical impressions of anabolic steroid users corroborate all this, as well as the other effects reported above.

Adverse Effects

Taking anabolic steroids is not without danger. Table 2 summarizes documented adverse effects. These reactions are noted when the drugs are taken in normally prescribed doses. Abusers often take them in many multiples of therapeutic doses. Any adverse effect listed in Table 2 should be considered as potentially serious, but the following are particularly dangerous.

Hepatotoxicity with or without jaundice is the major adverse effect. All anabolic steroid products warn that liver damage is possible. Specific pathologies include peliosis hepatis, hepatomas, and hepatic cholestasis. In the former condition, blood-engorged pouches accumulate in the liver. These may rupture, leading to hemorrhage and hepatic failure.

When jaundice occurs, it is frequently painless, so impending toxicity may not be clearly identified. Overall, there are few symptoms of hepatic injury that would lead an individual to seek medical assistance until it may be too late to prevent serious damage.

If anabolics are taken for a short period of time and they initiate liver disease, the condition may be reversible if the drugs are quickly discontinued. If they are continued, hepatotoxicity may be irreversible and fatal.

Endocrine disorders must also be considered among the more serious adverse reactions. Anabolic steroids produce profound effects upon endocrine functions, relating primarily to the masculinizing action. The drugs also inhibit release of gonadotropins from the pituitary, which in turn initiates menstrual cycle irregularities in women, and decreased sperm count, even sterility, in men. The sexual attractiveness that users perceive is therefore cosmetic, not functional. Women are at special risk because adverse effects such as deepened voice and male pattern baldness may be irreversible if the drugs are taken chronically.

Physiological changes include frequent mood changes, increased aggressiveness and inflated self esteem, irritable behavior, and a sense of invincibility. Recent evidence suggests that the drugs can lead to major psychiatric disturbances including manic or near-manic behavior.

Cardiovascular damage can be serious. Blood lipid changes include increased LDL-cholesterol and decreased HDL-cholesterol. Both can increase the risk of atherosclerosis and coronary heart disease with premature death.

Other cardiovascular problems result from the drugs' potent mineralocorticoid activity. This causes sodium retention with edema and hypertension. Edema can occur alone, or worsen congestive heart

TABLE 2

Adverse Effects Associated With Anabolic Steroid Use

Hepatic
- Peliosis hepatis
- Hepatoma
- Cholestatic jaundice
- Elevated liver-function test values

Endocrine
- Decreased luteinizing hormone
- Decreased follicle stimulating hormone
- Decreased testosterone
- Testicular atrophy
- Acne
- Gynecomastia
- Altered glucose tolerance
- Hyperinsulinism
- Decreased spermatogenesis
  - Decreased motility
  - Amorphous sperm
- Masculinization in women
  - Hoarsening of voice
  - Hirsutism
  - Menstrual irregularities
  - Enlarged clitoris
  - Decreased breast size
  - Alopecia

Cardiovascular
- Hypertension
- Increased low density lipoprotein (LDL) cholesterol
- Changes in triglyceride concentrations
- Fluid and water retention

Skeletal
- Epiphyseal closure

Subjective
- Aggressiveness, irritable behavior
- Psychiatric disturbances
- Changes in libido
- Muscle spasm
- Nervous tension
- Headache
- Changes in hair growth
- Dizziness
- Nausea
- Euphoria
- Rash
- Changes in appetite
- Urethritis
- Scrotal pain
- Increased urine output

failure. Some anabolic steroid users start taking diuretics (drugs they commonly add to their illicit drug regimen) to lose edematous fluid weight. However, this also subjects them to further drug adversity.

Skeletal abnormalities can be a major toxicity. Anabolic steroids can force closure of the epiphyses (ends) of long bones if administered during adolescence. When this occurs before completing the normal growth cycle, growth will be irreversibly stunted.

The potential for adverse effects is significant because doses are often many times that of normally prescribed doses. Chance for toxicity is increased further because of stacking and cycling dosage regimens. **Stacking** is a term used by athletes to describe concurrent use of more than one anabolic steroid, and may include both oral and parenteral drugs. A drug regimen may be tapered upward and back over a 4- to 18-week interval, typically before a competitive event.

Cycling describes the drug-free intervals which may last 4 to 6 weeks, or up to a year. Anabolic users plan this cycyling so that they are in peak shape for the actual competitive event.

The problem is compounded even further. Black market steroid injectables may be nonsterile and pyogenic, and contain unknown ingredients and/or concentrations. Products purported to be one steroid may be an entirely different chemical with its own toxicologic profile.

Steroid abusers also use a variety of other substances (e.g., growth hormone, human chorionic gonadotropin) to either enhance anabolic action, or modify steroidal side effects (e.g., diuretics). So the chance for inciting drug- induced toxic action is increased even more.

Regulations and Legislation

There has been sufficient interest in illicit use of anabolic steroids to bring state legislatures and medical boards to enact laws and regulations aimed at curtailing their use, and punishing offenders. Some states have placed anabolic steroids in the Controlled Substance classification. There is a number of individuals and organizations pushing the Federal Government to place these drugs under the jurisdiction of the DEA/ Controlled Substance Act.

At the state level (at the time of writing), California has placed anabolic steroids in Schedule III, Florida in Schedule IV, and Alabama in Schedule V. Colorado has defined their illegal distribution and use as being a misdemeanor for the first offense, and a felony for subsequent violations. Virginia states that illicit use is a misdemeanor, while Indiana, New Mexico, and Texas consider it to be a felony.

The Ohio Medical Practice Act prohibits physicians from prescribing or otherwise using anabolic steroids for other than legitimate uses, and their use in body building and for enhancing athletic performance is specifically prohibited. Other states that are reported to be considering legislation or regulation of anabolic steroids are Hawaii, Illinois, Louisiana, Massachusetts, New Jersey, New York, North Carolina, and Pennsylvania. Others will follow.

Another drug that should be mentioned along with anabolic steroids when discussing athletic-oriented abuse is human growth hormone (HGH). Two products — Humatrope and Protropin — are currently marketed.

These drugs, indicated for replacement therapy in prepubertal children whose endogenous production of HGH is inadequate, have become misused for body building purposes in adults.

The problem has increased to the point that their manufacturers (Lilly and Genentech) have removed the products from wholesaler distribution and restricted their availability to drop-shipment to legitimate accounts.

While increased control of these drugs will continue at the state level, it does not appear that either FDA or DEA is interested in placing anabolic steroids under the Controlled Substance Act. Spokespersons for the agencies have stated that the state is the proper place to regulate the use of anabolic steroids.

Overview and Summary

This article discussed the pharmacology and toxicology of anabolic steroids and offered insight into reasons why they are abused. It offered evidence that well-trained athletes who consume a high-calorie and high-protein diet can increase muscle mass and strength with anabolics.

It should be realized that at one time, product inserts stated that anabolic steroids did not enhance athletic performance. Experts on these drugs continue to argue the same point. But users know otherwise! And the majority of evidence strongly supports a positive protein anabolic effect.

Anabolics join other drugs that have been banned by the National Collegiate Athletic Association (NCAA), and International Olympics Committee. Their potential damaging action should be stressed to all athletes, especially youngsters. The health hazards associated with illicit anabolic drug use minimize real or perceived gains in performance, and overall, the harm they can cause far exceeds benefits.

Many people who use steroids are unaware of possible dangers. Others know the drugs can cause toxic damage, but they believe the problems will not appear until many years into the future, and they will deal with them then. Others reportedly argue that they are willing to accept toxicity later to gain an immediate, though temporary, period of drug-enhanced macho personality, or athletic competitive edge, today.

The most realistic means for reducing illicit anabolic steroid use is through education. Regulations alone, enacted without benefit of public educational programs, and threat of urine testing for drugs or rejection from competitive sports events, cannot curb the tide of illicit anabolic steroid use.

Pharmacists can help educate against anabolic steroid abuse. They can speak before high school assemblies and adult service groups to inform them of the seriousness of the situation. The FDA has prepared an educational program directed to potential users and high school coaches. This includes brochures, posters, a television news release, radio public service announcements, and an informational bulletin to high school coaches.

Dickinson's Pharmacy

Jim Dickinson

Just what pharmacy needs! Independent pharmacy has had more naysayers and merchants of doom than any other group in the health care market—including a vocal segment among its own ranks.

Yet despite years of gloom (remember "Pharmacy in the 21st Century's" prediction back in 1984 that by the year 2000, community independent retail pharmacists will be an extinct species?), most observers are now very upbeat about independents.

Your columnist has always been that way, partly because he's an independent himself, and partly because it only makes sense to recognize that you work at your best when you work for yourself.

What clouded the picture for a lot of folks these past few years was the large doubt about whether patients or society remains willing to pay pharmacists to work for themselves.

For a complex variety of different reasons, the answer is finally beginning to become clear—it's "Yes." Partly, that's because the elderly are more prosperous than in previous generations, and more knowledgeable, too—and they can force plans to give them what they want, for a price.

But in all the doubting that's been going on these past 20 years or so, independents have been dropping like flies, and the schools have been unable or unwilling to tell the pampered rising generation that there are rich rewards in the adversities of entrepreneurship.

Along comes the NARD Management Institute, backed by a grant from Marion Laboratories, and headed by D. C. Huffman, longtime executive director of the American College of Apothecaries.

Starting this summer, Huffman is relocating from ACA's Memphis home at the University of Tennessee, and moving (with ACA) into NARD's recently-enlarged Alexandria (VA) headquarters.

There, he will begin hiring staff and putting into motion a national, practical thinktank and network that in concept is exactly what pharmacy needs to reverse the rot and take advantage of the new trends in health care.

The Management Institute will be structured to take on practically any task, but initially Huffman sees it as having two most important early missions:

1. To assemble, develop and network management information that pharmacists need to be successful owners, and
2. To conduct or sponsor or cooperate in research to document pharmacy's reimbursement needs (e.g., cost-to-dispense studies, and cost-benefit analyses).

But all the other things the Management Institute has been set up to do sound equally exciting.

For example, Huffman is looking forward to setting up a graduate training program that will steer new pharmacists into retail ownership through structured experience with existing independent pharmacists around the country.

Other parallel programs will focus on personnel training for owners, convention workshops that give instruction on successful management skills, a speakers' bureau to recruit graduating pharmacists away from their present limited choices (hospital, manufacturer or chain employment), and a special ownership termination program that will seek to match retirement plans with the entrepreneurial plans of new pharmacists (e.g., a three-to-six-year "junior partnership" transitional plan).

Huffman intends to focus a lot of his efforts on the pharmacy administration departments of the nation's pharmacy schools, where tomorrow's pharmacists form their career goals, and their attitudes to independent pharmacy.

As if all this isn't enough, a glossy NARD brochure on the institute encapsulates yet another of Huffman's front-burner missions:

"Ongoing investigations of issues affecting the nation's independent retail pharmacists, including data-based research and technical information on such subjects as physician dispensing, drug product cost trends, mail-order pharmacy, prescription pricing methods, inventory control techniques, and electronic claims processing technologies."

And yet more: "Consultations with individual pharmacists on such subjects as pharmacy startup feasibility studies, merchandising, pricing strategies, inventory control, financial management, and human resource management, and innovative programs to serve home health care patients, long-term care facilities, and hospice programs."

It's just exactly what pharmacy has needed for a long time. Please support it—you'll only be supporting yourself.

This feature is presented on a grant from G.D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G.D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G.D. Searle & Co.

Head Lice Happen in the Nicest Families

Even your closest friends may not admit that they and their children have been infested with head lice and nits (lice eggs). Discovery of head lice can cause fear, embarrassment and guilt.

The exact incidence of head lice in the United States is unknown since most cases are unreported. However, estimates indicate that approximately six million Americans suffer an infestation of head lice each year. According to the National Pediculosis Association, there are more cases of pediculosis capitis (head lice) among school-aged children than all other communicable diseases combined, with the exception of the common cold.

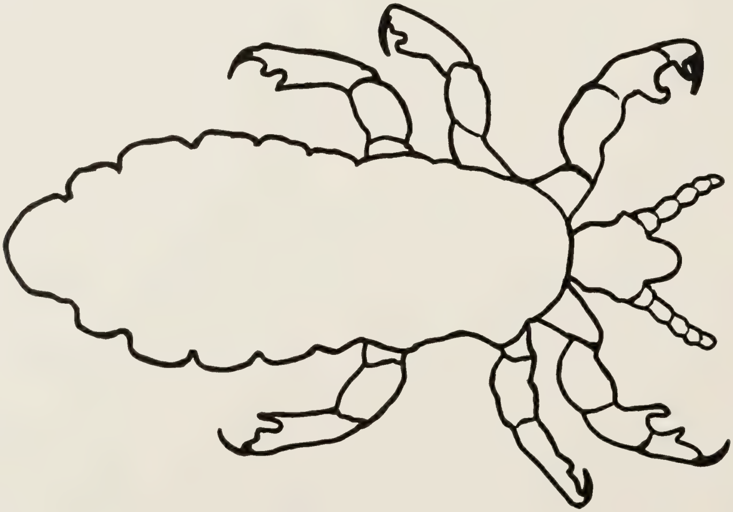
Head lice respect neither social station, age nor sex. A recent survey conducted from 1985 to 1987 indicated that head lice occurred in every geographic area of the United States, involving every level of society and ethnic group. Anyone may be susceptible to an infestation of head lice if they happen to come in contact with someone who has them. The poet Robert Burns, as he wrote in his poem, ''On a Lady's Bonnet at Church,'' was shocked to see a louse on ''Sae fine a Lady!''

Head lice infestation may occur in environments that are more filthy, but occurrence does not necessarily indicate a lack of cleanliness. Members of lower socioeconomic groups may be more likely than others to contract head lice because of the close proximity to others in which they live and the resulting increased possibility of exposure.

For reasons that are not entirely clear, school children from the ages of three to ten years appear to be most susceptible to head lice infestation. Girls and women appear to be more susceptible than men and some studies indicate a slight preference for long hair versus short. Millions of dollars are spent each year by health providers, school authorities and parents to screen, educate and treat children with head lice. Despite these efforts, the prevalence of head lice in the United States today is virtually unchanged from that of 40 years ago.

An initial reaction to the discovery of head lice is fear of disease. While it has been generally believed that head lice do not transmit diseases, some reports, including a 1979 study by Dr. L. L. Shaldt, indicate that head lice may carry causal organisms for typhus and relapsing fever. While these infections may seldom occur, head lice can cause intense itching and scratching which result in secondary infections.

Pharmacists reported that working mothers especially are struck with guilt when members of their families acquire head lice, according to a recent national survey by the Institute for Epidemiological Research. They worry that they are unable to keep their children and homes clean enough to prevent such an occurrence. Infestation, however, has nothing to do with cleanliness and can occur anytime a family member



Head Louse

comes in contact with someone who has head lice.

Perhaps the most common reaction of all is intense embarrassment. Pharmacists report that the discovery of head lice devastates some parents. They come into the drug store to purchase pediculicide treatments and wait until no one is around that counter to make their choice.

This intense embarrassment can be extremely dangerous in spreading the infestation. Regardless of feelings, parents should make sure that everyone who has been in contact with the family has been notified so that they can check for lice and get proper treatment before the highly contagious condition is spread.

Frequently when parents are courageous enough to speak out, they find that neighbors and friends have also encountered the problem and they work together to halt the local epidemic.

Modes of Transmission

Although infestation of man by head lice has been documented for thousands of years, the exact mode of transmission remains elusive. Contrary to popular beliefs, lice are incapable of flying, hopping, jumping or pole vaulting on toothpicks.

Head lice can move quickly (six to 30 cm/min) from hair to hair or scalp to scalp. Therefore it is thought that direct head-to-head contact is responsible for the majority of head lice transfer.

The group most frequently involved in such direct contact are school children who engage in physical games, and sit in crowded classrooms or school buses. Infested children may share combs, brushes, hats, scarves or clothing which could also be a mode of transfer. However, head lice require a temperature of 87 to 95 degrees F. and a human host for continued survival. They can survive for only 24 hours at 70 to 80 degrees F. off the human host.

In colder climates, head lice would be less likely to leave the warm human host for a colder inanimate object. Observations by a field entomologist indicate that lice may be more active in warmer seasons or warmer climates and may be readily found in towels, brushes or combs in those conditions.

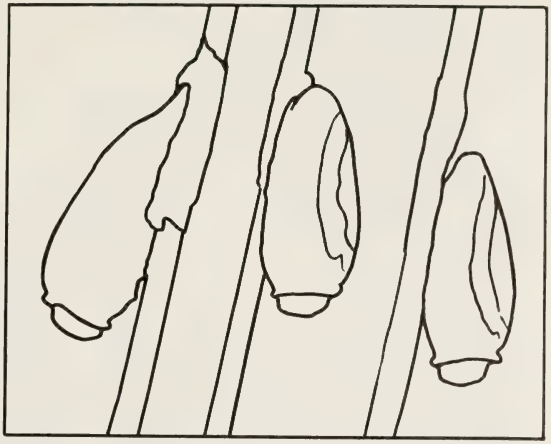
Treatment and Eradication

Getting rid of head lice is no easy matter and requires hours of concentrated effort from every family member.

The first step is to obtain a pediculicide shampoo to kill the lice. Some people obtain a prescription from their doctor, while others consult their local pharmacist for a recommendation. Instructions for using the shampoo should be carefully followed since some formulations can cause side effects or allergic reactions.

The second step, removing the nits (lice eggs), is equally important. Pediculicide shampoos kill most of the adult lice and 20 to 80 percent of the eggs. However, if eggs remain alive and hatch, the lice infestation can begin all over again.

The adult louse deposits her eggs on shafts of hair close to the scalp, securing them with a glue-like bond. Before now, the only way to remove nits has been to comb them out with a fine tooth comb. This can be painful and time consuming, especially in a family with several children.



Nits (Head Lice Eggs)

After treatment and removal of nits from the hair, many experts recommend the following measures to eradicate any head lice from articles of clothing, furniture, carpets and automobiles.

- Machine wash all clothing, towels and bed linens that the infested child has used in the last three days in hot water and dry in a hot dryer. If this is not possible, all these items should be dry cleaned.
- Pillows and stuffed animals that the child sleeps with should be put in a hot dryer for twenty minutes.
- Seal all items that cannot be washed or dried in a plastic bag for two to four weeks. This allows for any surviving lice or nits to complete their life cycle.
- Soak combs, brushes, rollers, barrettes, head bands or other hair items in hot soapy water for one hour.
- Vacuum floors, rugs, upholstered furniture and mattresses. Use of pediculicide sprays is discouraged since they are essentially pesticides and may be harmful to humans and pets.

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Summary.
Consult the package literature for prescribing information.

Indication: Lower respiratory infections, including pneumonia, caused by *Streptococcus pneumoniae, Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β-hemolytic streptococci)
Contraindication: Known allergy to cephalosporins
Warnings: CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN SENSITIVE PATIENTS PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS ALLERGENICITY POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS

Administer cautiously to allergic patients

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics It must be considered in differential diagnosis of antibiotic-associated diarrhea Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis

Precautions:
- Discontinue Ceclor in the event of allergic reactions to it
- Prolonged use may result in overgrowth of nonsusceptible organisms
- Positive direct Coombs' tests have been reported during treatment with cephalosporins
- Ceclor should be administered with caution in the presence of markedly impaired renal function Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include
- Gastrointestinal (mostly diarrhea) 2.5%
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] and toxic epidermal necrolysis or the above skin manifestations accompanied by arthritis/arthralgia, and frequently, fever). 1.5%, usually subside within a few days after cessation of therapy Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor No serious sequelae have been reported Antihistamines and corticosteroids appear to enhance resolution of the syndrome
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely
- Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertonia, dizziness, and somnolence have been reported
- Other eosinophilia, 2%, genital pruritus or vaginitis, less than 1%, and, rarely, thrombocytopenia

Abnormalities in laboratory results of uncertain etiology
- Slight elevations in hepatic enzymes
- Transient fluctuations in leukocyte count (especially in infants and children)
- Abnormal urinalysis; elevations in BUN or serum creatinine
- Positive direct Coombs' test
- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinitest* tablets but not with Tes-Tape* (glucose enzymatic test strip, Lilly). [061088L

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The Head Louse—Its Primeval Beginnings and Present Day Existence

The common head louse (pediculosis capitis) has its origins in the misty reaches of time as early as 136 to 65 million years ago. Its ancestors were probably similar to modern book lice and lived in the nests of early mammals or birds.

As the louse evolved through the ages, the tiny creature lost its wings, and its eyes became smaller or disappeared altogether. It developed sensory hairs on the body to detect and respond to changes in humidity.

The actual evolution of the louse is unknown, since there are no fossils to provide information other than one louse egg found in Baltic amber. However, it is believed that because the louse adapted itself specifically to each new host, its evolution mirrors the development of birds and mammals. This has resulted in some 3,300 species of small, parasitic insects of the order Phthiraptera. Of those, 400 species are members of a suborder known as Anoplura (sucking lice), which includes a family called Pediculidae—or human lice.

Three subspecies of lice are found on humans, and each inhabit a certain part of the body. Phthirus pubis, or the crab louse, infests the hairs of the pubic region. Pediculus humanus capitis lives in the hair of the head while pediculus humanus corporis lives on the body and in clothing.

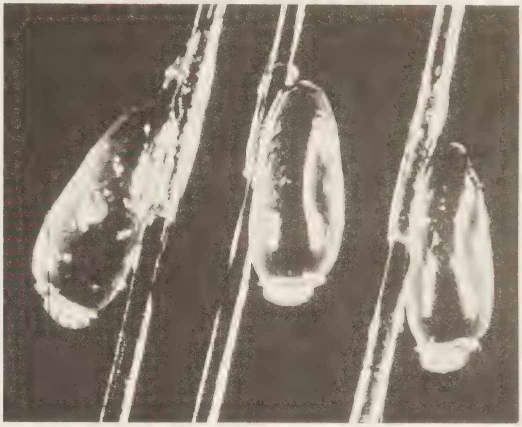
In medieval times, people believed that body lice were a sign of virility or holiness. As the carrier of typhus and relapsing fever (trench fever), body lice were responsible for some of the most disastrous epidemics in the history of man. Both Napoleon's army and the Russian army suffered as greatly from typhus carried by body lice as from hunger and exposure.

Typhus was a military-related problem as late as World War II, when entire cities were treated with DDT to halt epidemics.

While many believe that the human head louse does not spread disease, a 1979 study by Dr. L L. Sholdt indicates that the head louse may carry causal organisms for typhus or relapsing fever. The head louse lives its entire life on the hairy surface of the scalp, preferring areas behind the ears and at the nape of the neck.

Life Cycle of the Head Louse

The head louse ranges from two to three millimeters in length with three pairs of legs that are specially adapted to grasp scalp hair. On the average, an infested individual will be host to fewer than ten to 20 lice, although numbers in the hundreds have been reported.



Under optimal conditions, the average life expectancy of the head louse is 23 to 30 days. This duration is dependent on temperature (87 to 95 degrees F.) and access to human blood for feeding. The louse must feed every five hours, and therefore survival on inanimate objects is limited to only 24 hours at temperatures of 70 to 80 degrees F.

The head louse uses specially developed mouthpieces (stylets) to pierce the scalp. One stylet injects saliva with anticoagulant activity into the skin while the other stylet draws blood into the louse.

Although the feeding bite of the louse is painless, the injected saliva can cause irritation and pruritus. Intense itching can result in excoriations and secondary infections in the scalp. After multiple infestations and bites, an individual may manifest an allergic reaction to the louse bite. In severe infestations, the individual may develop swollen glands in the neck and/or under the arms.

The head louse is capable of reproduction only 12 hours after maturing into an adult. Twelve to twenty-four hours after mating, a female louse prepares to lay eggs in the hair.

Local Pharmacist Receives Recognition Award

Leon Catlett, R.Ph., Owner, Eakles Pharmacy, 201 Burhaws Boulvard, Hagerstown, Maryland, is a recipient of the MSD Pharmacist Recognition Award. He is a resident of Fairplay.

The award was established by Merck Sharp & Dohme (MSD), the U.S. prescription drug division of Merck & Co., to recognize business and civic achievements of pharmacists. Catlett was cited for his high professional standards in the field of pharmacy.

The award will be presented by Hugh Burkhart and Michael Durant, both of Merck Sharp & Dohme.

Continued from Page 13.

After sliding down the hair, a few inches away from the scalp, she then moves back up the hair shaft secreting a sticky glue-like substance from the genital opening which is followed by extrusion of an egg. This "glue" drys immediately, which firmly adheres the egg to the hair.

The egg case, which is also known as a "nit," is only 0.8 mm in size and has small holes to allow air and moisture in to the developing embryo. The nit looks as if it were encased in clear nail polish.

The female louse can lay three to six eggs on a single strand of hair as she crawls up to the scalp. On the average, the female head louse can lay 12 eggs a day.

Under optimal conditions, the egg or nit hatches within seven to ten days. Optimal conditions are defined as temperatures of 82 to 90 degrees F. and relative humidity of 70 to 90 percent. Prolonged temperatures under 65 degrees F. or over 97 degrees F. can be fatal to the eggs, although transient exposure to such temperatures merely slows the hatching time. Therefore incubation of the nit is dependent on either external human body heat or warm climate.

If untreated, over 90 percent of eggs will hatch successfully. Treatment with pediculicide shampoos will kill only 20 to 80 percent of the eggs, according to a review published in *Pediatric Dermatology* by Drs. Lawrence A. Schachner and Ronald C. Hansen. As a result, reinfestation from viable eggs can occur seven to ten days after treatment with a pediculicide.

An immature louse, called a nymph, emerges from the egg by piercing the egg case with its mouthpiece and popping out using air pressure. The nymph is as small as a tiny dot or period and requires a meal of blood within a few minutes after hatching in order to survive. The nymph undergoes three molting stages over eight to 12 days before becoming a mature louse. The new louse is capable of further reproduction as soon as 12 hours after the final molt.

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SCIENTISTS PROBE MYSTERIES OF TISSUE AND ORGAN INJURY; COMMON CAUSATIVE AGENT IDENTIFIED

Oxygen radicals are by-products of normal body metabolism that can damage or even destroy living cells. Injured cells release oxygen radicals which in turn attack cell membranes. Oxygen radicals have been implicated in a wide range of diseases, from stroke to cancer.

Scientists are actively studying ways of inhibiting oxygen radical reactions in the hope of preventing the formation of *lipid peroxides*—fats that are chemically altered by oxygen radical attack. Lipid peroxides are extremely potent chemical substances that can cause further damage and reduce blood flow in tissues. In addition, they hinder the normal process of metabolism and other celluar functions in tissues.

Free radicals and lipid peroxides were discovered by industrial rubber chemists and radiation biologists who were the first to characterize these reactions in the 1950s.

Because there is so much oxygen in body tissues and because oxygen tends to form highly reactive radicals by gaining extra electrons (negative charges), many body cells house these potential saboteurs to one's health.

Worse yet, normal metabolism is not the only source of unwanted free radicals. Air pollutants, pesticides, tobacco smoke, X-ray and ultraviolet radiation, cured, dehydrated and stored meats as well as fats used in frying at very high temperatures all add to the accumulation of oxygen radicals that can badly damage cells.

Living tissue can also be injured under conditions of too little or too much oxygen, and the cause again seems to be the presence of free radicals. Ischemia (oxygen deprivation) can develop in heart muscle or brain cells following a heart attack or stroke. Too much oxygen (hyperoxia) can occur when blood and oxygen rapidly enter an ischemic organ after transplantation or when a coronary artery is reopened.

Oxygen radicals are found in inflammatory conditions, including rheumatoid arthritis, and injuries to the head and spinal cord. Recent evidence also links them with the degeneration of brain cells in sufferers from Parkinson's disease.

Free radicals attack the cell primarily at three points. They target cellular proteins, lipids (fats) in the cell membrane and nucleic acids (the backbone of the DNA and RNA molecules).

The body has its own natural defenses, too. It produces enzymes — superoxide dismutase (SOD) and catalase — that convert free radicals to less toxic substances. One therapeutic strategy is to bolster these enzymes. Another is to employ components acting as free radical scavengers. Examples are vitamins E and C, which prevent injury to the cell by "mopping up" oxidants before they can do harm.

Lazaroids: New Steroid Derivatives Inhibit Lipid Peroxidation

Some scientists believe that free radicals and lipid peroxides play an important role in central nervous system (CNS) damage due to serious injury.

Researchers have found a surge in lipid peroxide production in brain tissues after CNS trauma. They have also found, in an experimental model of head injury and spinal cord damage, that improvement is hastened by a steroid hormone that inhibits lipid peroxidation—methylprednisolone. These findings suggest new posssibilities and a new rationale for the treatment of CNS trauma and stroke. (Stroke alone is responsible for more that 155,000 deaths in the United States each year, according to the American Heart Association.)

Present treatment options for CNS trauma are relatively crude. "The mainstay in treatment for severe head trauma is the use of mannitol or lasix, potent diuretics that help reduce edema (fluid accumulation) in the brain," says Wise Young, M.D., associate professor, department of neurosurgery and director of the neurosurgery laboratories at the New York University School of Medicine in New York City. "It is also possible to remove the injured part of the brain to allow room for swelling, thereby reducing intracranial pressure. Pentobarbitol has also been employed to put the injured brain into a kind of metabolic deep freeze (reducing brain cell activity), although this technique is controversial, especially in comatose patients where brain activity is already depressed."

Upjohn scientists built on the observation that corticosteroids inhibit lipid peroxidation. They developed a series of steroids that lack classical corticosteroid properties but are more active in their ability to inhibit lipid peroxidation and scavenge free radicals.

The members of this new class of lipid peroxidation inhibitors are called *lazaroids*. Lazaroids are now being studied in animal models for treating head trauma and spinal cord injury as well as stroke.

"Our studies indicate that lazaroids penetrate the cell membrane and scavenge free radicals by a mechanism similar to vitamin E, thereby preventing the destructive lipid peroxidation chain reaction," says Mark Braughler, Ph.D., senior research scientist, central nervous system diseases at The Upjohn Company.

Continued on Page 16.

Lazaroids Studied in Models of Central Nervous System Damage

Mice given an experimental lazaroid—U74006F—shortly after a severe head trauma did much better than those receiving only an inactive solution. Their survival rate was higher after one week. They also took a shorter time to recover their ability to maintain balance and to grip or to climb onto a string.

"We believe that U74006F's protective effect on the brain in this study is due to its ability to inhibit iron-dependent lipid peroxidation," says Edward Hall, Ph.D., senior research scientist, central nervous system diseases research at The Upjohn Company. "It is worth noting that U74006F, although a steroid derivative, does not produce many of the disturbing side effects of high-dose steroid treatment in animals."

In one study, the same experimental drug appeared to speed recovery from spinal injuries. In animal studies, U74006F prevented and reversed the progressive decline in spinal cord blood flow following a compressive injury. Most injuries to the human spinal cord involve crushing or bruising rather than cutting or tearing.

"The effects of U74006F on posttraumatic spinal cord recovery appear to be due to a vitamin-E-like antioxidant action—scavenging oxygen radicals—as well as an inhibitory effect on iron-dependent lipid peroxidation," adds Dr. Braughler.

Animal studies also show that lazaroids may be useful in treating stroke and cerebral hemorrhage. The nerve cell damage that occurs when the brain is starved of oxygen for a prolonged period is due in part to the generation of oxygen free radicals and lipid peroxides. U74006F kept blood flowing through the brain at twice the rate found in a control group following a period of oxygen deprivation.

"The largest potential group of patients that might benefit from the lazaroids are stroke victims where much of the brain remains intact, in contrast to the condition of the brain in severe head trauma cases," says Dr. Young. "Other than recommending an aspirin a day, there is really nothing that one can do now for a stroke victim during or immediately after an attack except to wait to see how things turn out."

Implicated in a wide variety of diseases, traumas and toxic conditions, oxygen free radicals are attracting more attention from researchers around the world than ever before. Clinical studies under way or now being planned will profoundly change the tools available for physicians to treat life-threatening resistant illnesses.

"Oxygen radical formation and lipid peroxidation may be the key phenomena occurring in large numbers of diseases," concludes Dr. Braughler. "Insight into their regulation represents a new frontier in biology and medicine."

OXYGEN FREE RADICALS LINKED TO TISSUE INJURY AND A VARIETY OF DISEASES

Vasco da Gama lost 65 percent of his crew to scurvy in 1498. In fact, the disease was the number-one killer of long-distance seafarers until a little more than two centuries ago. Then it was found that lemon juice and a diet free of rancid fat eliminated the scourge. Recent research has given those practices a scientific basis.

Such a diet helps to limit the formation of oxygen free radicals, dangerously reactive and short-lived byproducts of normal body metabolism that can damage living tissue. It also prevents lipid peroxidation, which makes fats rancid and is in part triggered by oxygen free radicals.

Today, antioxidants that prevent the proliferation of these free radicals are being studied as a new way of combating a host of diseases and pathological conditions. Recent evidence suggests that certain forms of cancer, heart disease, lung injury, arthritis and even aging to some extent involve oxygen radical reactions. Some scientists are studying the role of oxygen radicals in central nervous system trauma, including injuries to the head and spinal cord as well as stroke.

Numerous studies have implicated oxygen radicals in cellular injury. When the fatty (lipid) membranes that surround a cell are exposed to oxygen radicals, the radicals can punch holes in the cellular lipids, causing the cell to malfunction. This can result in cell membranes that are incapable of performing necessary physiological functions. The result can be cell death.

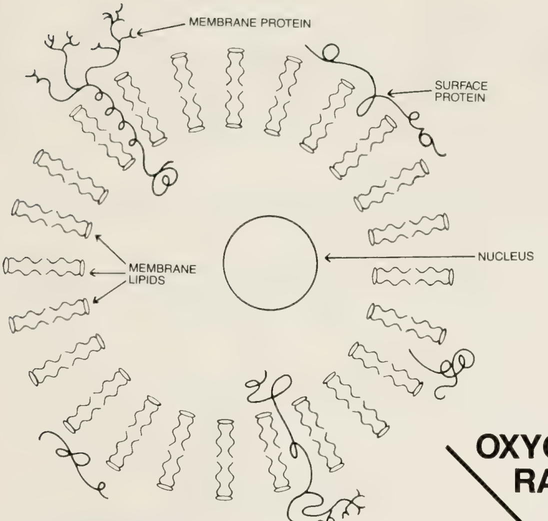
Perhaps the best evidence that oxygen free radicals are destructive to living tissue is that most cells have specific enzymes and other "radical scavengers" to protect them from excessive oxidants. However, when injury or illness overcomes these protective mechanisms, oxygen radicals begin to accumulate, signaling progression of disease.

Free Radicals in Head Injury, Spinal Cord Damage and Stroke

People in Japan, Finland and nonwhites in the United States have higher death rates from stroke compared with people in other nations (approximately 175 deaths per 100,000 population versus a worldwide mean of 100 deaths per 100,000). According to the American Heart Association, about 500,000 people suffer strokes each year in the U.S. (nonwhites and whites) and about 155,000 will die. This makes stroke the third leading killer in the U.S.

Head trauma is the major cause of death in Americans between 15 and 45 years of age. There are approximately 450,000 new cases each year, according to the National Institute of Neurological and Communicative Disorders and Stroke. And new cases of spinal

FIGURE 1: **HOW OXYGEN RADICALS CAUSE TISSUE INJURY**

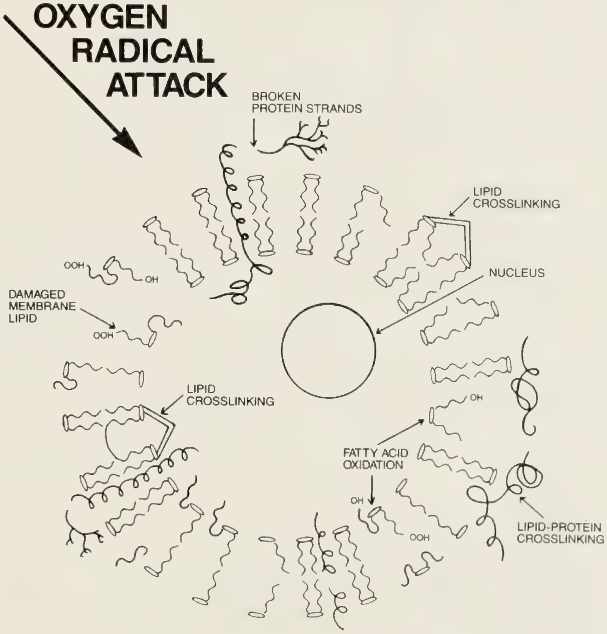

MEMBRANE PROTEIN
SURFACE PROTEIN
NUCLEUS
MEMBRANE LIPIDS

CROSS SECTION OF A HEALTHY CELL MEMBRANE

OXYGEN FREE RADICAL ATTACK ON CELL MEMBRANE

Sources of excess oxygen radicals include:

- tobacco smoke
- air pollution
- inflammation (from injury, trauma rheumatoid arthritis)
- cured, dehydrated and stored meat
- animal/vegetable fats used in industrial frying


OXYGEN RADICAL ATTACK
BROKEN PROTEIN STRANDS
LIPID CROSSLINKING
NUCLEUS
OOH
OH
DAMAGED MEMBRANE LIPID
OOH
LIPID CROSSLINKING
OH
FATTY ACID OXIDATION
OH
OOH
LIPID-PROTEIN CROSSLINKING

CROSS SECTION OF A CELL MEMBRANE WITH FREE RADICAL DAMAGE

Oxygen radicals are extremely reactive and short-lived by-products of body metabolism capable of damaging living tissue. Oxygen free radicals can attack cell membranes, causing damage to lipids and proteins. They cause oxidation of lipids (lipid peroxides—fats chemically altered by oxygen radicals that are unable to perform normal cellular functions). This process can impair a cell's ability to function or even destroy it.

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Continued from Page 16.

cord injury occur at the rate of about 10,000 each year. The majority of spinal injuries involve crushing rather than tearing or severing the spinal cord. The largest percentage of both head and spinal cord injuries is related to vehicular accidents.

Depending on the severity of the injury to the central nervous system, a certain number of brain cells may be damaged irreversibly. A common reaction to head injury is cerebral edema—an increase in the brain tissue fluids with consequent increase in pressure within the skull. It is believed to be a primary cause of death in severe head injuries.

Many people who survive a traumatic head injury end up severely brain damaged. Emergency room physicians may be able to keep patients alive following such incidents, but often they are helpless to prevent or restore lost neurological and motor function. Most survivors become almost totally dependent on institutions and loved ones for daily care.

Critical Secondary Damage May Be Preventable

A large proportion of the final damage in head injury and stroke is caused by a secondary process which involves lipid peroxidation, calcium movement into the cell, release of iron stored in hemoglobin and ferritin (an iron storage protein) and excess prostaglandin synthesis. This secondary injury process begins with lipid peroxidative damage to the membrane.

Brain cells in particular have a high lipid content. This makes them extremely susceptible to free radical reactions that can spread like wildfire through the nervous system following an initial trauma.

The loss of brain cells in Parkinson's disease also may be related to oxygen radical attack. Some of the evidence for this comes from animal studies. Oxygen radical scavengers (molecules that reduce the amount of free radicals in the body) protected the animals studied from brain damage due to free radicals generated by neurotoxins.

The National Institute of Neurological and Communicative Disorders and Stroke has recently funded a five-year, $10 million study to determine whether Parkinson's disease can be retarded by two drugs—deprenyl (an inhibitor of the oxygen-radical-forming enzyme monoamine oxidase) and tocopherol (vitamin E, a scavenger of oxygen radicals).

Parkinson's disease is characterized by a progressive loss of brain cells resulting in muscle stiffness and tremor. The condition afflicts more than a million people in the U.S. alone. The 800 participants in this study will be people in the early stages of the disease.

Some other studies now under way in academic and industrial research facilities seek alternate ways of countering free radical attack on the brain and spinal cord.

Paradoxical Effects of Oxygen in the Lungs

Deep-sea divers have long known that oxygen concentrations only slightly higher than that found in the air we breathe can cause serious lung damage and even death.

A primary site of oxygen-induced lung damage appears to be the endothelial cells that form the lining of the lungs. In one study, animals were exposed to the damaging effects of pure oxygen for several days. Before and during that time, some were injected with liposomes (microscopic lipid bubbles that can entrap drugs in their fatty core) containing superoxide dismutase (SOD) and catalase. These enzymes aided in the removal of oxygen radicals from their bodies and significantly prolonged the animals' survival.

In *emphysema*, the tiny alveoli (air sacs in the lungs) break down, reducing the surface area through which oxygen may diffuse into the blood and out. The walls of the alveoli also become less elastic.

Studies suggest that in emphysema the lungs are damaged by the immune system's secretion of enzymes that degrade proteins (proteolytic enzymes) as well as highly reactive oxygen radicals in the process. Both cigarette smoke and air pollutants stimulate this destructive cycle.

Enzymes that help eliminate reactive oxygen products from the body (e.g., catalase) can prevent lung injury from developing in animals treated with lung-damaging antibodies that stimulate the activity of their bodies' own white blood cells.

Adult respiratory distress syndrome (ARDS) is caused by lung injury following trauma, inhalation of stomach contents (especially gastric acid) that can occur when a person vomits while unconscious, severe infection and other factors. These events can cause protein and water to diffuse into the lungs (edema) through damaged blood vessels. Half of the 150,000 people afflicted each year die as a result.

Here, too, evidence suggests that oxygen radicals play a key role in the development of lung inflammation and ARDS. Further studies are needed to assess the therapeutic potential of antioxidant thereapy in human lung injury.

"In acute lung injury, oxygen free radicals appear to play a critical role in the initiation of damage to the endothelial and epithelial lining of the lung," says Kent

Johnson, M.D., associate professor, department of pathology, University of Michigan Medical School in Ann Arbor. "Human studies using antioxidant therapy such as vitamin E and SOD are presently being contemplated to deal more effectively with this life-threatening condition."

Organ Injury, Transplantation and Oxygen Deprivation

When arteries narrow, blood and oxygen supply to the major organs (heart, brain, kidney) is reduced. Cardiovascular diseases are the leading cause of death in the industrialized nations and are believed to be related to the generation of oxygen radicals. Oxidative damage to blood vessels by free radicals is thought to spur the buildup of artery-clogging cholesterol.

However, much of the organ injury that develops following a heart attack or stroke may actually occur at the time blood and oxygen are reintroduced to the tissue.

"In coronary-artery bypass grafting, regions of the heart that were exposed to ischemia (lack of oxygen) are suddenly reopened and subject to reoxygenation injury," says Joe McCord, Ph.D., professor and chairman, department of biochemistry at the University of South Alabama College of Medicine in Mobile. "Animal studies suggest that if superoxide dismutase (SOD) is circulated during renewed blood flow to reduce oxygen radical formation, it may be possible to improve the clinical outcome."

Antioxidant therapy may have a marked impact on organ transplantation as well.

"Human clinical studies are under way in which SOD and SOD analogs are being administered when the organ is reperfused with blood to determine the potential benefit of blocking oxygen radical formation in renal transplantation," adds Dr. McCord. "There is an increasing appreciation that oxygen radicals are involved in many pathological conditions. SOD and other antioxidants could provide scientists with new methods to study the disease process and to advance therapy." However, one limit to SOD is that it may not be useful in treating head injury or stroke since it does not effectively penetrate the blood-brain barrier.

Quelling Inflammation and Rheumatoid Arthritis

There is ample evidence that oxygen radicals play a major role in the inflammatory response. During an inflammatory reaction, a large number of cells called phagocytes can ingest mircroorganisms or other foreign particles that invade the site of injury or infection. Phagocytes release oxygen radicals that aid in digesting foreign particles.

In some inflammatory diseases, the body seems unable to distinguish foreign particles from its own cells. An example is rheumatoid arthritis, which afflicts one percent of the population. The lack of discrimination sets the phagocytes in motion around the joints, leading to the release of oxygen radicals and subsequent joint damage. In laboratory animals, treatment with scavengers of oxygen radicals reduces the number of inflammatory cells found in tissue surrounding the joints.

Protecting Against the Harmful Effects of Cancer Chemotherapy

By altering cellular DNA, anticancer drugs inhibit the growth of malignancies. Doxorubicin (Adriamycin, Adria) is an antibiotic drug used to treat cancers of the blood as well as solid tumors of the breast, ovary, thyroid and bone.

However, doxorubicin has a severe toxic effect on the heart that appears to be related to the generation of oxygen radicals that cause lipid peroxidation in cardiac tissue. In animal studies, this toxic effect can be blocked by drugs that help maintain the action of SOD and catalase—enzymes that help eliminate oxygen radicals.

Bleomycin (Blenoxane, Bristol-Myers) is an antibiotic used to treat testicular cancer and lymphoma. Bleomycin's toxic effects on tumor cells are mediated in part by oxygen radicals. By reducing the levels of SOD within the cell, scientists have been able to increase bleomycin's toxic effects on cancerous tissue in animals.

Dietary Fat, Lipid Peroxidation and Cancer

For the past 35 years, researchers have suspected a link between dietary fat and cancer. More recently, scientists have speculated that cancer of the colon and cancer of the breast are related to increased animal fat intake. Fat accounts for more than 40 percent of the calories consumed in the typical U.S. diet.

Dietary fat is easily oxidized, resulting in the production of lipid peroxides as well as a variety of potent carcinogens. Studies have shown that dietary lipid peroxides (oxidized cholesterol and unsaturated fatty acids) as well as free radicals may participate in the development of cancer in humans.

While it is virtually impossible to maintain a diet free of lipid peroxides, excessive amounts of some foods are likely to introduce lipid peroxides into your body. Cured, dehydrated and stored meats and animal or vegetable fats used in industrial frying contain high levels of lipid peroxide by-products.

There are a number of oxygen radical scavengers in our diets that provide some degree of antioxidant protection and conceivably are anticarcinogens as well. They include vitamins E and C, beta-carotene (found in carrots), selenium (a dietary mineral) and glutathione (an antioxidant present in various plant and animal tissues). However, the precise amounts that confer the greatest protection are unknown.

Oxygen Radicals and Aging

The average life expectancy in the U.S. is about 75 years, according to the U.S. National Center for Health Statistics. Life expectancy in Japan is 74 years, Sweden 73 years and the U.K. 71 years. Some individuals live as many as 20 or more years longer. The huge variability in longevity suggests that some unrecognized factors may be involved. One theory holds that cellular aging is related to the accumulation of free radicals and lipid peroxides. Vital organs and blood vessels are the main targets for uncontrolled lipid peroxidation that generates defective molecules and leads to aging and cell death.

Age pigments (lipofuscins) consist mostly of oxidized lipids. Found in abundance in the cells of adults, they are thought to be formed as a result of free radical damage to the cell.

Animals given free radical scavengers or protective antioxidant enzymes survive longer than animals fed only a diet high in oxidized fats. Studies suggest antioxidants can inhibit the production of certain cancers as well as reduce atherosclerosis (fatty deposits in the arteries) in experimental animals.

Cardiovascular diseases and cancer are the leading causes of death in the industrialized world. If antioxidant therapy proves as effective in people as it appears to be in animals, life expectancy could be greatly prolonged. But confirmation must await further clinical study.

There is good scientific evidence that oxygen free radicals can cause serious damage to cellular lipids, proteins and DNA. Unchecked, lipid peroxidation can be a pervasive and highly toxic process to cells.

The relationship between oxygen radicals, lipid peroxidation and cellular damage is now under careful study by a diverse group of scientists working on critical medical problems around the world. As a result, researchers are beginning to understand the mechanisms by which oxygen radicals can injure tissue and are seeking to develop novel antioxidant countermeasures.

The next step is for scientists to begin testing more potent and specific oxygen radical scavengers in people suffering from illnesses linked to excess free radical production.

GLOSSARY OF OXYGEN RADICAL TERMS

ADULT RESPIRATORY DISTRESS SYNDROME (ARDS): A condition in which the lungs are filled with fluid that contains protein and red blood cells. This condition can be caused by trauma or shock, inhalation of stomach contents (especially acidic gastric juice), hydrocarbon fluids (such as gasoline), high concentrations of oxygen, drug overdose and severe infection (septicemia). Once damage has occurred to the blood vessels in the lungs, the results are similar, regardless of the cause. About half of the people afflicted with ARDS die of respiratory failure.

ANTIOXIDANT: One of a variety of natural or synthetic substances that can prevent or delay the oxygen-caused deterioration of a molecule. Vegetable oils and many commercial foods contain antioxidants (e.g., BHA, BHT) as preservatives.

CATALASE: This enzyme, found in most cells throughout the body, causes the breakdown of hydrogen peroxide to water. Hydrogen peroxide is capable of forming potent oxygen radicals in the body.

CATALASE: This enzyme, found in most cells throughout the body, causes the breakdown of hydrogen peroxide to water. Hydrogen peroxide is capable of forming potent oxygen radicals in the body.

CELL MEMBRANE: The protective, semipermeable biological barrier that envelops a cell, composed primarily of lipids and proteins.

DNA: Deoxyribonucleic acid, or DNA, is the genetic material of all cells. DNA is composed of a chain of nitrogen-based subunits (nucleic acids) found in the chromosomes of a cell.

EDEMA: The presence of abnormally large amounts of fluid in certain tissues is a condition that can be localized or widespread. Damage to blood vessels that allows them to leak proteins and water into tissue spaces is one frequent cause of edema.

ELECTRON: A negatively charged electric particle in orbit around the nucleus of an atom. Electrons associated with a particular atom ordinarily travel in orbitals containing two electrons spinning in opposite directions. Electrons may move from an orbital (orbit) around the nucleus of one atom to an orbital around the nucleus of another, thereby changing the nature of atoms and hence molecules.

FATTY ACIDS: Lipids that are required by biological systems for survival, reproduction and growth. They are used by cell membranes for structural, physiological and metabolic purposes. Because of their chemical structure, they are very susceptible to attack by oxygen radicals.

HYDROXYL RADICAL: A highly reactive by-product of oxygen metabolism—a combination of oxygen and one hydrogen atom. The hydroxyl radical (HO°) is formed in biological systems when hydrogen peroxide reacts with trace metals (iron or iodide) found in the bloodstream.

ISCHEMIA: A deficiency of oxygen in a particular tissue, usually due to constriction or obstruction of a blood vessel.

LAZAROIDS: Novel group of steroid derivatives which lack hormonal activity (as well as hormonal side effects) but act as both scavengers of active oxygen species and inhibitors of iron-dependent lipids peroxidation. Preliminary studies in animals suggest that lazaroids may be effective in reducing long-term damage due to stroke, head trauma and spinal injury.

LIPID PEROXIDATION: The process in which oxygen free radicals attack the fatty outer coating (membrane) of the cell. Lipid peroxides formed from normal lipids (fats) of the cell membrane or body are unable to perform the necessary metabolic and structural roles that fats ordinarily play.

LIPOFUSCINS: A class of fatty pigments consisting mostly of oxidized fats that are found in abundance in the cells of adults. Some studies suggest that lipofuscins are responsible for the aging process in a cell.

METABOLISM: The sum of all chemical and physical processes that break down foodstuffs, permitting energy to be made available for the needs of an organism.

NEUTROPHILS: Granular white blood cells that participate in the immune response to foreign substances. Neutrophils are part of the body's defense system and produce oxygen radicals to destroy invaders.

NUCLEIC ACIDS: A group of substances composed of phosphoric acid, sugars and purine and pyrimidine bases constituting the backbones of DNA (or RNA) molecules.

OXIDATION: Refers to the state of being oxidized or the act of oxidizing another substance. A molecule is oxidized when it loses electrons (negative charges); thus it becomes more positively charged. Oxidation is always coupled with reduction (gain of electrons) —one atom losses electrons, another gains them.

OXYGEN FREE RADICALS: Highly reactive (due to an unpaired electron) and unstable by-products of oxygen metabolism with extremely short half-lives and capable of causing damage or death to cells.

OXYGEN SPECIES: A category of active oxygen molecules distinct from atmospheric oxygen that are capable of causing tissue injury. Members of this class include the superoxide radical, hydrogen peroxide and singlet oxygen.

PHAGOCYTE: A protective cell that can ingest and digest microorganisms or other foreign substances. Phagocytes release oxygen radicals when they engulf foreign matter.

RNA: Ribonucleic acid, or RNA—found in all living cells—transmits information from DNA to the protein-forming system of the cell. RNA is composed of a chain of nitrogen-based subunits (nucleic acids).

SCAVENGER: A substance that can combine with and absorb electrons from free radicals, thereby protecting cells or other substances from radical attack.

SUPEROXIDE: A common and reactive form of oxygen (O_2^-) in biological reactions that is formed when molecular oxygen gains a single electron. Superoxide radicals can attack susceptible biological targets (lipids, proteins, nucleic acids).

SUPEROXIDE DISMUTASE (SOD): An enzyme found in many cells that converts superoxide radicals to less toxic agents.

SINGLET OXYGEN: These highly reactive and unstable oxygen species ($^1O_2$) are formed when an unpaired electron absorbs enough energy (radiation, etc.) to reverse the direction of spin in its orbit. Singlet oxygen reacts readily with fatty acids and other molecules, causing damage to cells.

BIOLOGICAL SIGNIFICANCE OF OXYGEN RADICALS: DESTRUCTIVE MOLECULES YIELD THERAPEUTIC INSIGHT

The most important element in the air we breathe—oxygen—may not be as innocent as it seems.

Oxygen is vital to human life. However, some forms of it can damage living tissue. *Oxygen free radicals* are by-products of normal body metabolism that can destroy a cell or impair its ability to function.

Tissue and organ injury, inflammation, cancer, cardiovascular disease and aging all have been tied to an excess of oxygen free radicals. Perhaps the single most important defense against all these diseases will turn out to be new drugs that combat the proliferation of oxygen radicals and the damage they may spawn. Such a scientific advancement may one day revolutionize how physicians think about and treat disease and injury.

In moderation, however, oxygen radicals serve some necessary and desirable functions in the body as well. For example, biological systems employ them to help destroy invading organisms such as bacterial or viral infections. Oxygen radicals also take part in chemical reactions that require the transfer of energy from one molecule to the next, as in the routine metabolic breakdown of food to extract energy.

Consequently, the body has evolved protective mechanisms designed to keep oxygen radical formation in check.

Understanding oxygen radicals—what they are, how they function, where they come from, what damage they can cause and how to block their undesirable effects in the body—is yielding insight that promises to have a profound impact on the future of medicine.

Continued on Page 25. . . .

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TABLE 1: **SOME CONDITIONS LINKED TO OXYGEN RADICALS**

Conditions	Number of New Cases In the United States per Year
CARDIOVASCULAR DISEASES	**63,400,000***
RHEUMATOID ARTHRITIS	**2,100,000****
CENTRAL NERVOUS SYSTEM:	
HEAD TRAUMA	**450,000**
SPINAL CORD INJURY	**10,000**
STROKE	**500,000**
EMPHYSEMA	**191,000**
CANCER	**930,000**
ADULT RESPIRATORY DISTRESS SYNDROME	**150,000**
MAJOR ORGAN TRANSPLANTS (does not include tissue transplants)	**38,541**
INFLAMMATION	—
AGING	—

*Estimated total number of people with cardiovascular diseases as of 1984.
**Estimated total number of people with rheumatoid arthritis as of 1986.

Excessive production of oxygen radicals—highly reactive and unstable by-products of oxygen metabolism—are tied to tissue damage in a variety of conditions. Scientists are developing novel therapeutic strategies to mop up or "scavenge" oxygen radicals and bolster enzymes that convert radicals to less toxic substances.

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What Are Oxygen Free Radicals?

Oxygen free radicals are potentially destructive, reactive and short-lived forms of oxygen, with a special affinity for lipids (fats), proteins and nucleic acids (DNA and RNA backbone).

Oxygen radicals are produced when a molecule gains an extra electron (a negatively charged particle). For instance, the extra electron turns atmospheric oxygen, O_2, into the negatively charged superoxide radical O_2^-. In a stable chemical bond, every orbit around an atomic nucleus contains a pair of electrons, but in an oxygen radical, the addition of one unpaired electron renders the molecule chemically very reactive.

In addition to the superoxide radical, there are also other derivative oxygen species (oxidants, or oxidizing agents capable of taking electrons from other molecules) that are even more reactive and hence more damaging to biological molecules. Examples are the hydroxyl radical ($HO^{\cdot}$)—composed of hydrogen and oxygen—and singlet oxygen ($^1O_2$)—formed when oxygen absorbs excess energy. Some of these oxygen-derived species depend on iron and other minerals present in the blood for their production. Oxygen radicals are derivatives of one of the most abundant elements known to man.

There is good evidence that oxygen radicals attack living organisms on several fronts. Data suggest that oxygen radicals can:

- Damage lipids (fats) within cells
- Fragment DNA strands, producing genetic mutations
- Damage proteins, resulting in the loss of biological activity
- Destroy bacterial and animal cells in laboratory experiments
- Produce inflammation
- Cause severe injury or cell death in the lungs
- Damage blood vessels
- Decrease the activity and availability of neurotransmitters (brain chemicals that carry messages from one nerve cell to the next)

The odd number of electrons found in an oxygen radical confers some unique properties to it. In particular, a radical can attack certain molecules that venture into its vicinity. While lipids are a primary target of oxygen radicals, proteins and nucleic acids (DNA backbone) also risk free radical damage.

What Is Lipid Peroxidation and Why Is It Important?

Free radical attack on lipids produces *lipid peroxides* that, in turn, can disrupt the structure and function of the cell membrane. (Cell membranes are semipermeable biological barriers composed of lipids and some protein that envelop a cell like the shell of an egg.) In addition to serving metabolic purposes, lipids also are integral structural components of the cell membrane. They are the foundation that holds the cell together.

More specifically, oxygen radicals can initiate lipid peroxidation by binding to portions of fatty acids (which occur in the cell membrane) and then reacting further to form lipid peroxides. A self-perpetuating chemical chain reaction may result, converting virtually all the cell's lipids to lipid peroxides.

"Lipid peroxides interfere with membrane functioning in biological systems under radical stress," says Barry Halliwell, Ph.D., research fellow in preventive medicine, department of biochemistry, King's College, University of London in England.

Some of the specific deleterious effects that lipid peroxidation can have on a cell include:

- Cell swelling due to the disrupted flow of minerals into and out of the cell
- Movement of calcium into the cell which results in the activation of specific enzymes (protein molecules that accelerate specific biological reactions) that can disrupt cell function
- Disruption of proteins and carbohydrates

There is evidence that lipid peroxides exist in diseased tissue. However, it is not clear whether lipid peroxidation is actually the cause of cell damage or is itself the result of injury or disease (possibly causing further damage). Some researchers argue that probably both processes occur simultaneously.

Oxygen radicals are implicated in cancer and inflammatory diseases in two more ways. Certain cancers may be linked to the ability of oxygen radicals to cause genetic mutation. A DNA molecule exposed to oxygen radicals can suffer extensive damage.

Inflamed joints are loaded with disease-fighting but, in this case, misguided neutrophils (white blood cells) that produce oxygen radicals. This associates oxygen radicals with the joint damage that occurs in rheumatoid arthritis. With fuller knowledge, scientists should be able to develop anti-inflammatory drugs that will combat these substances in the fluid of an infected joint.

Sources of Oxygen Radicals in the Body

Oxygen can freely penetrate the membranes of most cells in the body. And most of the oxygen taken up by human cells is converted to water by the action of enzymes within cells. However, some of these enzyme systems "leak" negatively charged electrons onto oxygen molecules. Since oxygen readily accepts electrons, the superoxide radical (O_2^-) and other damaging oxidants can easily form.

In animal studies, the rate at which the superoxide radical forms increases as the concentration of oxygen rises. Furthermore, there is evidence that potent oxidizing agents exist in the vapor expired in human breath, lending support to the theory that oxygen radicals exist in the body.

Other sources of oxygen free radicals in the body include air pollution (particularly carbon monoxide, nitric oxide, unburnt hydrocarbons and ozone), inflammation, metal-containing proteins as well as other sources of metal (potent electron-transferring agents) and various oxidizing enzymes that are involved in cellular metabolism. For example, hemoglobin in red blood cells contains iron. Even trace amounts of iron catalyze the formation of oxygen radicals.

Cellular Defenses and Antioxidant Molecules

Apparently to protect us from these potentially damaging substances, antioxidant molecules are present throughout the body.

Contending with oxygen free radicals is part of the price we pay for having evolved in a world where oxygen is the basic element of respiratory exchange. Our continued survival is and has been dependent on our ability to defend ourselves against the ravages of an "oxidizing" environment. The step-by-step process of energy metabolism is designed so that biological oxidation occurs as a controlled, orderly process. Rapid, uncontrolled oxidation occurring in the body would be akin to a match burning itself out in a few moments.

The primary weapons the body has against free radical damage are the ability (1) to convert cellular oxidants to water and oxygen (nonradical) through the action of various enzymatic defenses and (2) to reduce the concentration of radicals in the body by the action of free radical *scavengers*.

Any molecule that can react with a free radical in such a way as to reduce the concentration of free radicals can be termed a scavenger.

Over the past two decades, scientists have discovered ways in which oxygen radical formation can be inhibited. Vitamin E—a fat-soluble vitamin that can penetrate lipid membranes—can remove the dangerous unpaired electron from an oxygen radical (superoxide, lipid peroxide, other oxidants). The transfer of electrons reduces a free radical or lipid peroxide to a less toxic form. Vitamin C (a water-soluble antioxidant that can get into the fluid compartments of a cell) has similar scavenging properties and helps regenerate vitamin E to its active scavenger form.

Free radical scavengers, like vitamins E and C, do not actually halt the body's production of oxidants. Instead, they protect the cell by becoming oxidized themselves (electrons can be donated to oxygen radicals by the scavengers), thereby sparing surrounding healthy tissue.

In addition to vitamins E and C, other antioxidant molecules can be found throughout the body and in our diet. Beta-carotene (found chiefly in carrots) protects body fat from oxidation. Uric acid, found in high concentrations in blood and urine, is also a potent radical scavenger. Human blood plasma contains ceruloplasmin, a copper-containing plasma protein that has been shown to be a powerful inhibitor of lipid peroxidation.

The main enzymatic mechanism for clearing superoxide radicals from the body is the superoxide dismutase (SOD) class of enzymes. Superoxide dismutase enzymes are composed of metal-containing proteins (copper, zinc, manganese, iron) that convert oxygen radicals to hydrogen peroxide. Hydrogen peroxide can then be converted to water and oxygen by the enzyme catalase and by the action of other enzymes that require the presence of the dietary mineral selenium and the tripeptide (three amino acid molecules tied together) glutathione, found in many animal and plant tissues.

Scientists are gaining a better understanding of disease and injury through the study of oxygen-derived free radicals and the damage they may cause. Free radicals can impair a cell's structure and function. The study of antioxidants and their ability to protect the body from the ravages of uncontrolled free radical formation is now moving from the laboratory into the clinic.

The results from this next stage of investigation promise to aid in the fight against a multitude of diseases and tissue injury that have thus far largely evaded conventional treatment.

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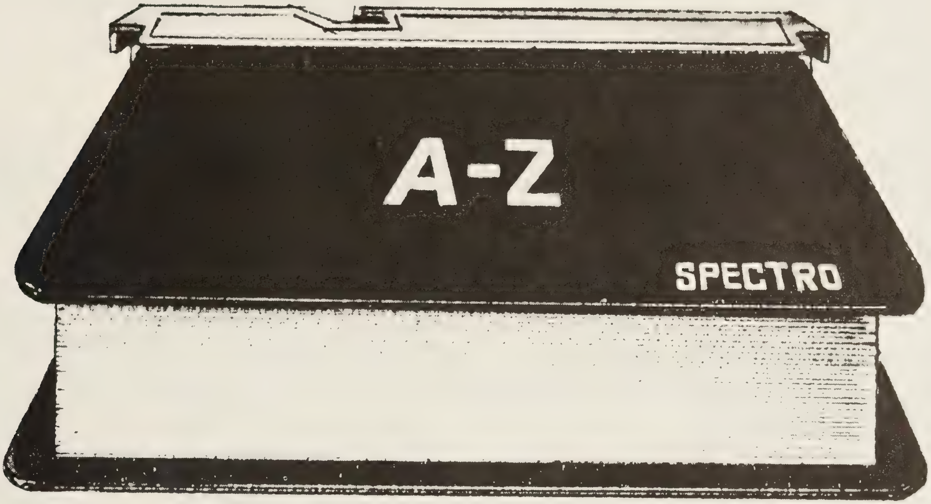

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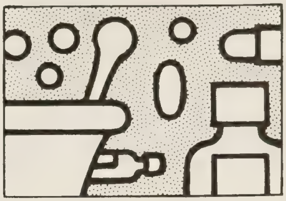
Things You Should Know FOR YOUR GOOD HEALTH



Fall Clean-Up

While you are doing your fall cleaning, isn't it about time you cleaned your medicine chest of drugs that have lost their potency or became toxic?

There are few over-the-counter or prescribed drugs that have an indefinite shelf life. Syrup of ipecac and alcohol are among the exceptions.

Aspirin seems to last a long time, but it begins to lose it's potency in about two years. Antiseptics and ointments last two or three years.

The state health department advises you to date all medicines when you buy them unless it is a prescription drug that is to be taken continuously until all of it is used. Keep drugs in original containers with labels, and read the label each time you use the drug.

The state health department recommends that drug containers have safety lids, but that is not always practical. It's not only those with arthritic hands who have trouble opening these containers. If you have medications in your home without safety lids, keep them out of the reach of children.

Old drugs should be discarded. Some drug bottles have an expiration date, so you know when to get rid of them. You can tell when others are losing their potency when they become crumbly, change color, odor, or consistency.

Aspirin smells vinegary when it loses its potency. Liquids might dry out, and many drugs darken with age. hen you discard drugs, flush them down the toilet, and rinse out the bottle. Never throw drugs in the trash can—it is too easy for children to get to them.

Don't stock up on over-the-counter drugs when they are on sale. Buy only the amount your family will use in a reasonable length of time. This is true of prescription drugs, too. There is an added danger here—and that is self-diagnosis. If you get similar symptoms at a later date, you may start taking that medication again, and it may not be the medication you should be taking at all. If you, or a member of your family, is sick enough to warrant taking a prescription drug, a doctor should be prescribing it.

Now, you've got your medicine cabinet cleaned out. Where should you store the drugs you are going to keep. Not in the medicine cabinet, because of the fluctuation in heat and steam in the bathroom. Drugs stored in such conditions lose their potency or become toxic faster than those stored in a cool, dry place.

The ideal place would be in a locked box in a cool closet in a bedroom or hall. If there are no children in the home, drugs could be stored in an unlocked box, but keep in mind that children are climbers from toddler stage on—so put them on a high shelf—out of reach of visiting children.

If you want more information on storing drugs safely, **Ask Your Pharmacist,** *Its For Your Good Health.*

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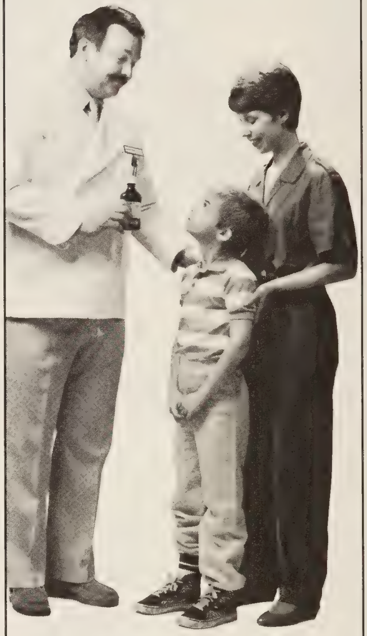
Millions Of Children Take Their Medicines. Wrong.



Speak Up For Children
Talk About Prescriptions

A message from:

National Council on Patient
Information and Education
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Washington, DC 20001

Recent court decisions and their impact on community and hospital pharmacy are the topics of a recently released videotape program available from Hoechst-Roussel Pharmaceuticals.

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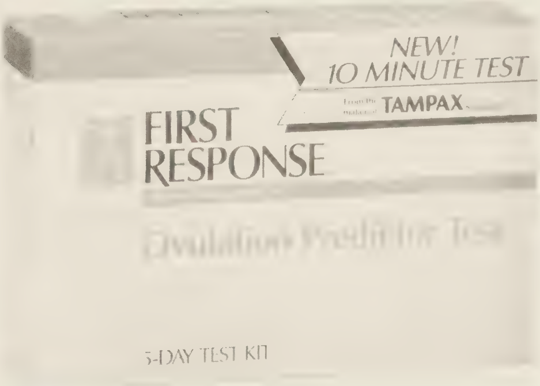
E. E. Dickinson has introduced a Transparent Cleansing Bar with Aloe, the first of its newly created "Naturals" line. Plans to support the new product include an introductory promotion featuring a "Try Me Free Offer" on the single bar and a rebate of $1 on the three-bar pack.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Continuing Education Quiz

The Maryland Pharmacist **SEPTEMBER 1989**

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by December 31, 1989. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

Name ______________________________

Social Security Number ______________________________

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Is this program used to meet your mandatory CE? [ ] Yes [ ] No

Did this article achieve its stated objectives? [ ] Yes [ ] No

How long did it take you to complete the program? __________ minutes

Anabolic Steroids in Sports

1. Which of the following is an FDA-approved indication for the use of anabolic steroids?
   a. Anemia
   b. Hirsutism
   c. Jaundice
   d. Weight Loss

2. Anabolic steroids exert their major adverse effect on the:
   a. kidneys.
   b. liver.
   c. skin.
   d. lungs.

3. All of the following products contain nandrolone EXCEPT:
   a. Anabolin.
   b. Anavar.
   c. Androlone.
   d. Hybolin.

4. Anabolic steroids are molecular manipulations of:
   a. aldosterone.
   b. hydrocortisone.
   c. progesterone.
   d. testosterone.

5. In order for anabolic steroids to be effective in building muscle mass, the individual must ingest a diet rich in protein and:
   a. calories.
   b. fat.
   c. iron.
   d. milk.

6. Which of the following anabolic steroids has the highest anabolic:androgenic ratio and therefore is least likely to cause androgenic effects?
   a. Nandrolone
   b. Oxandrolone
   c. Oxymetholone
   d. Stanozolol

7. The pharmacological action of anabolic steroids is linked most closely with which of the following enzymes?
   a. Carbonic anhydrase
   b. G-6-P dehydrogenase
   c. Monoamine oxidase
   d. RNA polymerase

8. The term "stacking" as it relates to the illicit use of anabolic steroids is best defined as:
   a. concurrent use of more than one anabolic steroid.
   b. the ability to place more weights on the bar when bench pressing.
   c. getting a greater "high" when taking anabolic steroids.
   d. drug-free periods of 4 to 6 weeks.

9. Adverse effects of anabolic steroids include all of the following EXCEPT:
   a. decreased production of luteinizing hormone.
   b. decreased spermatogenesis.
   c. decreased LDL-cholesterol.
   d. decreased production of follicle stimulating hormone.

10. Anabolism is the component of metabolism during which the body converts:
    a. complex substances into more simple forms.
    b. simple substances into more complex forms.

Classified

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

PHARMACY RX ITEMS, broken containers, fast and medium movers for sale at reduced prices. Contact Preston Pharmacy at (301) 673-2318. Pharmacist closing store.

PHARMACY COMPUTER System for sale. 3PM 40/40, 5 years old, Best offer. Call Brian at Penn-Dol, (301) 669-2424.

EVERY SUNDAY MORNING at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the pharmacy public relations program, "Your Best Neighbor," the oldest continuous public service show in Baltimore.

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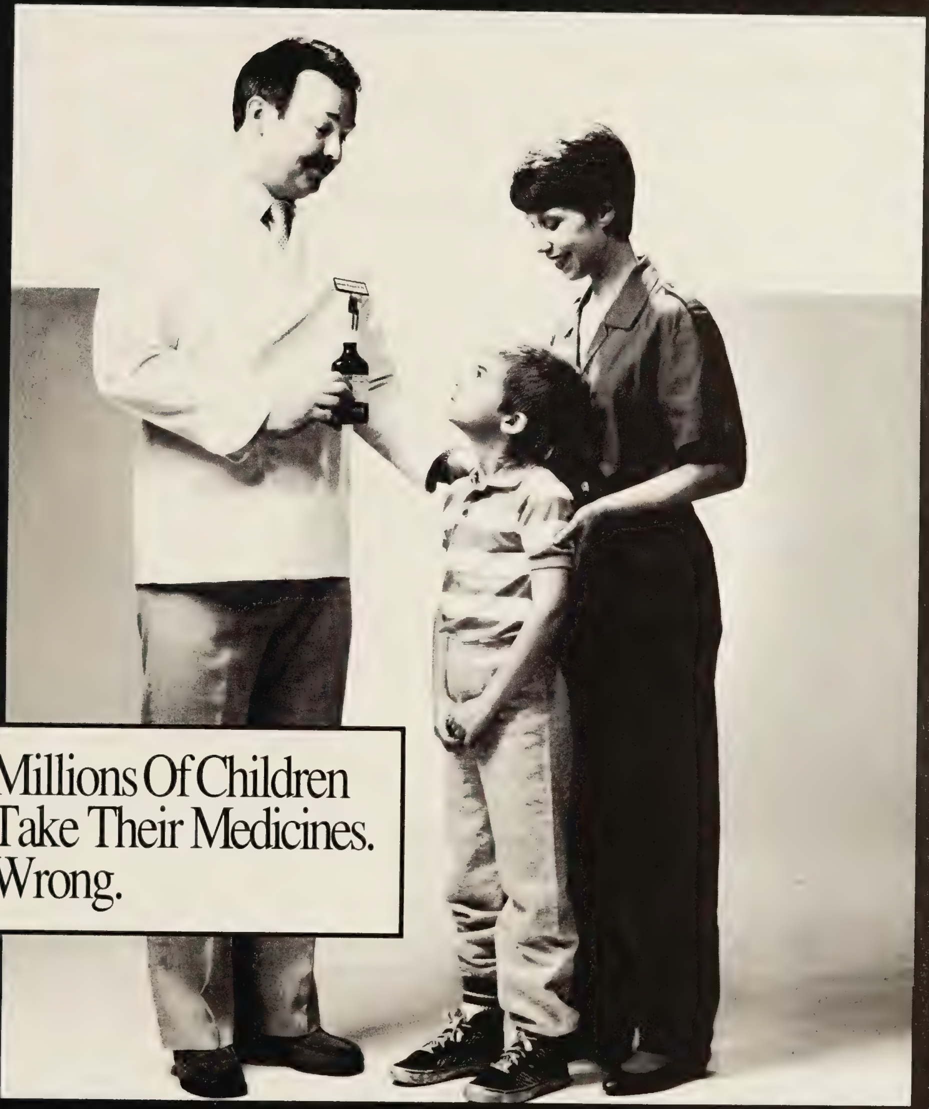

Millions Of Children Take Their Medicines. Wrong.

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SPEAK UP AMERICA
Talk About Prescriptions

Guest Commentary

Dear Colleague:

I invite you to participate in the fourth annual "Talk About Prescriptions" Month this October, 1989. Sponsored by the National Council on Patient Information and Education, "Talk About Prescriptions" month is a campaign to increase awareness about the proper use of prescriptions medicines.

"Speak Up America: Talk About Prescriptions" is the theme for this October's special needs of all Americans who use prescription medicines—the young, old and in-between.

Please give "Talk About Prescriptions" Month your full support and participation. One effective way to participate is to distribute copies of the many patient education aids included in this issue of *The Maryland Pharmacist* to your customers and patients.

"Talk About Prescriptions" Month is the ideal forum to highlight your activities and expertise in medication communication. Join with thousands of organizations to sponsor information and education activities this October and beyond.

Pharmacists are an integral part of the success of NCPIE. Don't hesitate to call NCPIE's office to discuss participation in "Talk About Prescriptions" Month. Call Ray Bullman or Bob Bachman at (202) 347-6711.

Thank you for your participation.

Sincerely,

Paul G. Rogers

Chairman, NCPIE

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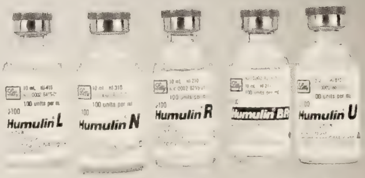

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This issue of *The Maryland Pharmacist*'s continuing education article will enable you to earn 1 credit hour (0.1 CEU) towards fulfillment of your C.E. requirements. Read the article carefully and then complete the quiz that appears on page 30. Return your answers to the MPhA offices as instructed on the quiz.

Correspondence Course

The New Drugs of 1988-89

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Gossel

Wuest

Goals

The goals of this lesson are to identify and discuss new drugs approved by FDA and/or marketed during 1988 and 1989.

Objectives

At the conclusion of this lesson, the participant should be able to:

1. exhibit knowledge of the drugs discussed by pharmacologic and therapeutic classification;
2. choose the indications, mechanism of action, benefits and limitations of the drugs discussed;
3. identify adverse effects and drug interactions associated with the drugs; and
4. demonstrate an ability to counsel patients on these new drugs.

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Twenty new chemical entities were approved as drugs by FDA during 1988 (Table 1). Of these, 13 were sanctioned in the last two weeks of the year. The 20 new chemical entities compare favorably with previous years: 21 in 1987, 20 in 1986, 30 in 1985, and 22 in 1984.

The FDA new drug classification system depicted in Table 1 indicates the categorization of a new drug for the particular indication(s) that the manufacturer requested when it filed its New Drug Application (NDA) for that drug. Following marketing, as additional uses may be approved, the designation will change.

For example, misoprostol was granted "1A" status for the indication listed in Table 1. If the drug is approved for treatment of peptic ulcer disease, it will then be designated as a "4", appropriate to the indication as listed at the bottom of Table 1.

The following discussion will review the new drugs of 1988-89 by pharmacologic classification.

Cardiovascular

CARTEOLOL (Cartrol)

Carteolol is a long-acting, nonselective beta-adrenergic blocker with intrinsic sympathomimetic activity (ISA). Because of the latter property, it does not depress the resting heart rate as much as other beta blockers devoid of ISA. Compared to other commercially available beta-adrenergic blockers, it is closest to pindolol (Visken) in pharmacologic action.

Carteolol is scheduled to be available in three strengths: 2.5 mg, 5 mg, and 10 mg tablets, and will be taken once a day for treatment of hypertension. Doses above 10 mg per day are unlikely to produce additional benefits in therapy. Since the market for beta blockers is competitive, its manufacturer is contemplating whether it will release the drug.

Adverse effects from carteolol are similar to other beta-adrenergic blockers. These include aggravation of congestive heart failure, headache, dizziness and drowsiness, hypotension, insomnia and/or anxiety. Nausea, vomiting, and abdominal pain are also reported. Carteolol appears to penetrate the blood brain barrier poorly. Consequently, it may cause fewer adverse effects on the central nervous system than some of the other drugs in its class.

NICARDIPINE (Cardene)

A calcium channel blocker chemically related to nifedipine, nicardipine is indicated for treatment of angina pectoris and hypertension. The drug was developed in Japan and is reported to be the largest selling calcium channel blocker there.

As with other calcium channel blockers, nicardipine inhibits influx of calcium ions into smooth muscle. This relaxes vascular smooth muscle and lowers blood pressure. Its action in

Table 1
The New Drugs of 1988-89

Name	Sponsor	Classification	Indications/Use
Astemizole (Hismanal)	Janssen	1C	Non-sedating H_1 antagonist
Butyl methoxy-dibenzoylmethane and Padimate-O (Photoplex)	Herbert	1C	OTC full-spectrum sunscreen
Carteolol (Cartrol)	Abbott	1C	Antihypertensive
Cefotiam (Ceradon)	Takeda	1C	Antibiotic
Diclofenac (Voltaren)	Ciba-Geigy	1C	NSAID for arthritis
Exametazime (Ceretec)	Amersham	1B	Imaging agent
Ethanolamine (Ethamolin)	Glaxo	1B	Prevention of rebleeding of esophageal varices
Flutamide* (Eulexin)	Schering	1B	Antiandrogen for treating prostatic carcinoma
Gadopentetate dimeglumine (Magnevist)	Berlex	1B	Imaging Agent
Ifosfamide (Ifex)	Bristol	1A	Third-line chemotherapy of germ cell testicular cancer
Ioversol (Optiray)	Mallinckrodt	1C	Imaging agent
Mesna (Mesnex)	Asta	1B	Prevention of ifosfamide-induced hemorrhagic cystitis
Misoprostol (Cytotec)	Searle	1A	Prevention of NSAID-induced gastric ulcers
Naftifine (Naftin)	Herbert	1C	Antifungal
Nicardipine (Cardene)	Syntex	1C	Antihypertensive and antianginal
Nimodipine (Nimotop)	Miles	1A	Subarachnoid hemorrhage
Nizatidine (Axid)	Lilly	1C	H_2-antagonist
Octreotide (Sandostatin)	Sandoz	1A	Symptomatic treatment of carcinoid tumors and VIPomas
Oxiconazole (Oxistat)	Glaxo	1C	Antifungal
Pergolide (Permax)	Lilly	1B	Adjunct to levodopa/carbidopa in the treatment of Parkinsonism
Tiopronin (Thiola)	Mission Pharmacal	1B	Kidney stone formation

*Approved 1989.

FDA new drug classification system: 1 = new chemical entity, 2 = new salt, 3 = new combination, 4 = new dosage form, 5 = generic drug, 6 = new indication; A = significant therapeutic gain, B = moderate therapeutic gain, C = little or no therapeutic gain.

treating angina is related to its ability to relax coronary vascular smooth muscle at serum levels that cause little or no negative inotropic effects. Nicardipine has only minimal effects on sinoatrial and atrioventricular nodal function. It therefore has little cardiac depressant activity and does not have anti-arrhythmic action. It has also been used for Raynaud's disease and congestive heart failure.

Nicardipine can cause wide swings in blood pressure between peak and trough levels. Physicians are therefore advised to monitor pressure responses at peak (1 to 2 hours) following initiation of therapy, and trough (i.e., at equilibrium, approximately 8 hours) to assess patient response to therapy.

Side effects are characteristic for the calcium channel blocker group. These include actions associated with vasodilation (headache, flushing, and edema), cardiac palpitations, hypotension, depression, dyspnea, and anxiety.

NIMODIPINE (Nimotop)

Another calcium channel blocker, nimodipine reduces the incidence of neurological deficit following spasm of the cerebral arteries that often accompanies subarachnoid hemorrhage. The outcome of preventing cerebral artery spasm is improvement of cerebral blood flow. Nimodipine differs from other calcium channel blockers in that it readily crosses the blood-brain barrier, and is relatively selective for cerebral arteries.

The drug is available in 30 mg soft gelatin capsules. At a dose of 2 capsules every 4 hours for 21 days, therapy should begin 4 days after the subarachnoid hemorrhage occurs. Patients are at greatest risk for cerebral artery spasm beginning about day 4, through the next 21 days.

The market potential for this product for its current indication is limited. There are reportedly 25,000 patients per year with diagnosed subarachnoid hemorrhage, with about 15,000 survivors available for treatment.

Potential indications include occlusive stroke, dementia, and age-associated memory deficit. Nimodipine is in Phase III clinical trial for treatment of Alzheimer's disease. It has also demonstrated some effectiveness in preventing migraine.

ETHANOLAMINE OLEATE (Ethamolin)

This sclerosing agent is indicated for prevention of rebleeding of esophageal varices. It is not indicated for treatment of esophageal varices that have not bled. Unfortunately, it does not benefit portal hypertension, the primary cause of esophageal varices.

Antineoplastics and Associated Drugs

FLUTAMIDE (Eulexin)

The first orally effective androgen antagonist, flutamide is indicated for use in conjunction with LH-RH agonists such as leuprolide (Lupron) for treatment of metastatic prostate carcinoma. Both drugs must be started together to achieve maximal results.

In one clinical trial of over 600 persons, patients given both leuprolide and flutamide survived 7 months longer, on average, than other patients receiving leuprolide alone. Seven months may not sound like much time, but to the patient, it can be a lifetime.

Leuprolide must be administered parenterally; flutamide is taken orally.

Approximately 12 percent of patients experience diarrhea. Other adverse effects include those expected from chemical castration: hot flashes, decreased libido, impotence, and gynecomastia (enlarged, painful breasts in males). Unlike castration which is irreversible, the result of treatment with these drugs is reversible should the patient go into remission. Approximately 12 percent of patients experience diarrhea.

IFOSFAMIDE (Ifex)

Ifosfamide is an alkylating agent with chemical structure and pharmacologic action similar to cyclophosphamide. It has demonstrated significant activity alone and in combination with other antineoplastic agents to treat a variety of cancers. It was approved for combination therapy, along with mesna, for refractive germ cell testicular cancer.

Ifosfamide is converted to an active metabolite, ifosfamide mustard. Another metabolite, acreolein, is devoid of anti-tumor activity but is extremely irritating to the renal tissues. Acreolein is the suspected cause of hematuria, urinary frequency, and dysuria that are common with both ifosfamide and cyclophosphamide. Cyclophosphamide is also partly converted to acreolein.

MESNA (Mesnex)

Mesnex was approved for concomitant use with ifosfamide to protect against renal tissue toxicity associated with the alkylating agent. It does not possess significant pharmacologic activity on other systems. The drug is, however, available in other countries as a mucolytic agent.

It is proposed that mesnex acts by inactivating acrolein, a metabolite of ifosfamide and cyclophosphamide, thereby preventing renal tissue toxicity. The cytostatic activity of other active metabolites of ifosfamide and cyclophosphamide is not affected.

The most significant adverse effects include dose-related nausea, vomiting and diarrhea. A false-positive ketone urea test with Multistix has been reported. It has therefore been suggested that this action be used as a check to ensure that patients are actually taking mesna.

OCTREOTIDE (Sandostatin)

Octreotide is a long-acting (t1/2 = 1.5 hours), synthetic analog of naturally-produced somatostatin (t1/2 = 1 to 2 minutes). Somatostatin helps regulate water and electrolyte balance in the intestine. It also slows GI transit time, and suppresses secretion of a number of biologically active substances into the intestine. These include gastrin, pancreatic polypeptide, insulin, glucagon, secretin, motilin, and vasoactive intestinal peptide (VIP). Octreotide exerts similar activity.

It is the latter substance, VIP, that appears to be most closely linked to octreotide's action. In excess, VIP stimulates increased secretion of water into the intestine. Since water comprises the greatest bulk of feces, the result is severe diarrhea. VIP is also a potent vasodilator.

Octreotide is, therefore, indicated for treatment of chronic and severe diarrhea and flushing that are associated with carcinoid tumors and vasoactive intestinal peptide-secreting tumors (VIPomas). The official uses for the drug are directed at a limited patient population, estimated to be 2,500 or less. It is available in pre-filled syringes for self-injection.

The action of octreotide is broad and its indications may someday be extended. Table 2 summarizes the end result of octreotide activity on a variety of tissues.

The most frequent side effect is nausea. Pain at the site of injection, loose stools (surprising, since this is the condition being treated), abdominal pain/discomfort, and vomiting are adverse effects reported above the 3 percent level.

Table 2
Pharmacologic Effects of Octreotide

Site or Function	Effect
Blood flow to gut	Decreases
Gut hormone	Inhibits gastric acid, gastric inhibitory peptide, gastrin, secretin, vasoactive secreting peptide
Gut absorption	Decreases carbohydrate absorption, increases water absorption and electrolyte absorption
Intestinal motility	Decreases
Pancreas	Inhibits insulin, glucagon, pancreatic bicarbonate, pancreatic polypeptide
Pituitary	Inhibit growth hormone and thyrotropin secretion

Adapted from Rosenberg JM: *Drug Intell Clin Pharm* 22:748,1988

Anti-Infectives

NAFTIFINE (Naftin)

Naftifine belongs to the broad-spectrum antifungal group called allylamines. The cream product is indicated for treatment of tinea cruris (Jock itch), tinea corporis (ringworm of the body), and tinea pedis (athlete's foot). One advantage is that it has a quicker onset of action than other topical antifungal products currently available.

OXICONAZOLE (Oxistat)

A member of the imidazole group of antifungals which has activity against both tinea and candida, oxiconazole is similar to other antifungals already available. The drug is reportedly under study for incorporation into a vaginal sponge product intended for treating yeast infections.

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MISOPROSTOL (Cytotec)

Misoprostol is indicated for prevention of NSAID-induced gastric ulcer in persons at high risk of complications from gastric ulceration. These include geriatric patients, smokers, and others with a past history of ulcers or GI bleeding.

A synthetic analog of naturally produced prostaglandins, misoprostol exerts similar action, but has a longer biological half-life. One of the many roles of prostaglandins is to protect the gastric mucosa from erosion by acid and pepsin. By inhibiting prostaglandins, NSAIDs can cause GI bleeding, even ulceration. Misoprostol restores protection by maintaining the production of mucus and bicarbonate ions by gastric epithelial cells. This prevents NSAID-induced destruction of these cells and ulceration. It is estimated that approximately 200,000 cases of NSAID-related GI bleeding, with 10,000 to 20,000 deaths from complications, occur each year in the U.S.

A strong marketing point for misoprostol is that approximately 60 percent or more of NSAID-induced ulcers are asymptomatic. This is especially true for geriatric patients. The problem is understandable because NSAIDs are analgesic and can mask early warning signs of ulceration.

Misoprostol enters the market place in competition with other agents used extensively for treatment and prevention of gastric ulcers, the H_2-antagonists and sucralfate. While they have proven effectiveness against peptic ulcer disease, they are not officially indicated for NSAID-induced GI hemorrhage.

Misoprostol is the first prostaglandin analog approved for use on the GI tract. It has been marketed elsewhere since 1985, and is currently approved in more than 40 countries, mostly for use in treatment of peptic ulcer disease. Seven other countries currently permit marketing for coadministration with NSAIDs.

Primary adverse effects include diarrhea and abdominal pain (4 to 13 percent). The most prominent adverse effect is increased uterine contractibility with abortion (11 percent) when the drug is taken in the first trimester of pregnancy. This is of importance to physicians and pharmacists since misoprostol lists one of the most extensive contraindications and warnings relative to use in pregnancy. The manufacturer strongly recommends that Cytotec *only* be dispensed in its original, unit-of-use packaging that contains appropriate patient advice.

DICLOFENAC (Voltaren) and FLURBIPROFIN (Ansaid)

Diclofenac was marketed in late 1988, along with flurbiprofen (Ansaid). While these NSAIDs are new to the U.S., both have been available elsewhere for over a decade (diclofenac since 1974). Diclofenac is reportedly the largest selling NSAID worldwide with nearly 12 percent of market share.

The pharmacologic action attributed to diclofenac, classified chemically as a phenylacetic acid derivative, is basically the same as for other NSAIDs, i.e., inhibition of prostaglandin synthesis. The prostaglandins they inhibit are mediators of inflammation. By reducing synthesis, NSAIDs curtail inflammation and further damage to the diseased joint.

A claim for diclofenac is that it causes less GI bleeding/ulceration than aspirin. Ibuprofen is the other NSAID which is permitted by FDA to make the same claim. Undoubtedly this is a major reason for its widespread use outside the U.S., and the impact it has made in this country since release. It is associated with elevations in liver-function tests in about 15 percent of patients.

Flurbiprofen, the other NSAID released in 1988, had already been available as the sodium salt in another dosage form, an ophthalmic solution (Ocufen). Its pharmacologic action is similar to other NSAIDs, but it is unique in that its labeling does not recommend periodic liver function tests be performed. Although the drug was developed by Boots, Upjohn has cross-licensing rights as with ibuprofen. In this instance, however, a product exchange was made with Boots for exclusive rights to market flurbiprofen. In return, Upjohn granted Boots marketing rights for its enteric coated erythromycin product, E-Mycin.

Other New Drugs

ASTEMIZOLE (Hismanal)

Astemizole is the second nonsedating H_1-antagonist to be approved for marketing in the U.S. It has a long half-life, allowing for once-daily dosing. Its "1C" rating compares it favorably, but without significant therapeutic gain, to terfenadine (Seldane).

BUTYL METHOXYDIBENZOYLMETHANE + PADIMATE O (Photoplex)

This combination of 3 percent butyl methoxydibenzoylmethane and 7 percent padimate O provides sunscreen protection against both UVB and UVA radiation. The product, Photoplex, is therefore described as a "full spectrum" sunscreen. Unlike previous sunscreens, it extends protection to photosensitive patients against the longer wavelengths of ultraviolet radiation (UVA). UVA radiation is currently thought to be more potentially damaging than UVB, because of its greater availability.

NIZATIDINE (Axid)

The fourth H_2-antagonist to be marketed in the U.S., nizatidine joins the group with similar therapeutic activity. It has not yet demonstrated the drug interactions associated with cimetidine, and to lesser extent, ranitidine. Its availability in a patient "convenience pack" may offer an advantage in improvement of patient compliance. Unlike other H_2-antagonists, nizatidine is available only as an oral dosage form.

PERGOLIDE (Permax)

A long-acting dopamine agonist similar to bromocriptine, pergolide was approved for concurrent use with carbidopa/levodopa (Sinemet) for treatment of Parkinson's disease. Pergolide may be useful in individuals who have experienced a decrease in responsiveness to levodopa. The drug may also be effective when used alone.

TIOPRONIN (Thiola)

Tiopronin is indicated for treatment of severe homozygous cystinuria, an autosomal recessive disorder in which excessive amounts of the amino acid are excreted. Because of its low solubility in urine, cystine stone formation may occur. The drug complexes with cystine to solubilize it. Clinical trials to date summarize tiopronin to be as effective as penicillamine in decreasing cystine excretion.

Tiopronin may cause adverse effects similar to penicillamine. These include GI responses, blood dyscrasias, myasthenia gravis, nephrotic syndrome, and a lupus-like reaction.

TALK ABOUT
PRESCRIPTIONS
MONTH

Medicine Misuse: A Family Problem

Medicine misuse creates major health problems for the whole family regardless of age and sex, according to the National Council on Patient Information and Education (NCPIE).

NCPIE notes that American women receive 60% of the 1.6 billion prescriptions dispensed annually and suffer an estimated 58% of all adverse drug reactions. Millions of American children put their health at risk because they take (or are given) their medicines wrong. Older consumers take over 400 million prescriptions and suffer more than half of the deaths reported due to adverse drug reactions.

Poor medicine use can run in families when people do not talk to each other or to their health care professionals about safe and effective medicine use. The Council, a not-for-profit coalition of 250 health professional, consumer, government, voluntary health and industry groups, reports that family members of all ages pay a serious price.

Children and Teenagers. Improper medicine use has been associated with decreased survival in children with cancer, decreased function or failure of pediatric renal transplants, continued seizures in children with epilepsy, uncontrolled diabetes, asthma, and juvenile arthritis, and the persistence of curable infections. Up to 4.6% of pediatric hospital admissions have been related to medicine use; up to 44.4% of these problems have been severe or fatal. Avoidable side effects occur in more than 11% of cases.

Grandparents. A new report by Richard Kusserow, Inspector General of the U.S. Department of Health and Human Services, states that ''mismedication'' hospitalized about 243,000 older adults for adverse drug reactions in 1985 and produces 32,000 hip fractures from drug induced falls each year.

Parents. Young and middle aged adults who do not use their medicines properly do not control chronic diseases such as high blood pressure and diabetes, setting up serious complications later in life. Improper medicine use can even harm unborn children, or fail to relieve the symptoms of conditions such as arthritis and gastrointestinal disease. Young and middle-aged adults, sometimes called the ''sandwich generation,'' often face the added responsibilities of ensuring safe and effective medication use by their children and their own parents or in-laws.

According to the Council, a family with poor medicine taking practices is like a family with a history of other health problems. If one family member has it, health professionals should consider others in the family at risk.

''Improper medicine use is a problem that we can solve'', says NCPIE Chairman, Paul G. Rogers. ''Health care professionals can talk with the whole family to make proper medicine use a family health priority. Proper medicine use includes better communication about medicines among family members and between families and their health care professionals. This is the theme of NCPIE's 4th national ''Talk About Prescriptions'' Month in October, 1989. We call the campaign 'Speak Up America: Talk About Prescriptions.' ''

NCPIE has prepared a free guide for participation in ''Talk About Prescriptions'' Month this October. To receive a guide write: ''Talk About Prescriptions''/ NCPIE/666 Eleventh Street, N.W./Suite 810/Washington, D.C. 20001.

SPEAK UP AMERICA
Talk About Prescriptions

Children and The Improper Use of Medicines: A Widespread Problem with Serious Consequences

What is the Problem?

Every year nearly 200 million prescriptions are written for children. About 13 million children take prescription medicines in any 2-week period. Yet studies show that almost half are not taking them properly, even when they have serious diseases.

They stop taking their medicines too soon, don't take all the doses at the right times, refuse to take them at all, or get too large a dose for safety.

TALK ABOUT PRESCRIPTIONS MONTH

What Are the Consequences?

Dangerous Health Outcomes. When children use medicines improperly, lives can be lost, treatable chronic diseases can remain uncontrolled, and acute illnesses can needlessly continue or recur. Cancer patients suffer decreased survival rates, and kidney transplants can fail. Diabetes, epilepsy and asthma can remain uncontrolled, and infections can continue or recur.

Inadvertent Treatment Errors. Unrecognized noncompliance can lead physicians to increase a dose unnecessarily or to change a correct treatment approach.

Life-Threatening Unintended Effects. Sometimes medicine errors lead to hospitalization and severe or fatal consequences. The most common problems include stopping antibiotics and seizure medicines too soon.

Avoidable Unpleasant Side Effects. The most common include diarrhea, other gastrointestinal complaints, skin rashes, nervousness and depression.

Unnecessary Diagnostic and Treatment Costs. Financial costs of poor medication use include the costs of unused medicines, unnecessary diagnostic and treatment costs, and resulting higher insurance premiums.

Greater Risk of Accidental Poisoning. The accumulation of unused medicines due to non-adherence increases the possibility of accidental poisoning, especially in households with young children.

Key Factors Leading to the Problem

1. Parents, children, and health professionals often don't communicate with each other adequately about medicine use. Practitioners often do not provide adequate counseling about medicines, and parents frequently do not ask questions. Children rarely take part in the discussion.
2. Many parents don't adequately monitor their children's medicine using. Children's autonomy often correlates with poor adherence.
3. Modern family life (busy schedules, disorganized lifestyles) may hinder safe and effective use of medicines.
4. Some parents and children have negative attitudes about medicines. Many children don't understand the difference between legitimate medicines and illegal drugs. Parents have a variety of fears about childrens' medicine use.
5. Some parents are poor role models for medicine use. They don't communicate well with their health professionals or follow treatment properly when they take medicines themselves.
6. Psycho-social barriers (school or extra curricular activity schedules, peer pressure, adolescent developmental factors) contribute to misuse.
7. Schools and day care centers are inadequately involved in educating and cooperating with parents about legitimate medicine use.

Recommendations for Action

The National Council on Patient Information and Education (NCPIE) has launched a nationwide campaign to address medication misuse among children and teens. The first step in NCPIE's campaign was to review the professional literature on the topic and present what is currently known about improper medicine use, its causes, and its consequences for children and teenagers.

NCPIE's latest report, "Children and America's Other Drug Problem: Guidelines for Improving Prescription Medicine Use Among Children and Teenagers," makes the following recommendations for action:

1. Improve communication among health care professionals, parents and children about the safe and effective use of medicines.

Studies show that effective patient-professional communication about medicines improves compliance with therapy. There is also some evidence that children can be a productive part of this interchange. Because NCPIE's campaign is focusing on this recommendation, the report includes guidelines for action for all of the groups that can help solve the problem: Parents, grandparents, and other caretakers of children; physicians, pharmacists, nurses and other health professionals; teachers and schools.

2. Raise awareness among health professionals of the need to educate children, their parents, and caregivers more effectively about how to use medicines properly.

Before parents or the caregivers of children can administer medicines properly, they need complete instructions such as how much to give, when to give it, and for how long. They need to understand the benefits of following the prescribed treatment, the potential consequences of failing to do so, and how to overcome barriers to compliance that might occur.

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TALK ABOUT
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CHILDREN AND MEDICINE USE

Continued from page 11.

Although many health professionals provide some instructions for medicine use, more thorough and effective medication counseling needs to become a medical priority.

3. Urge adult Americans to become good role models for taking medicines safely and effectively.

By setting a good example for proper medicine use, parents can teach their children a health habit with lifelong importance. Adults should make proper medication-taking, including active communication with health professionals, a family priority, a cornerstone of good health like a proper diet, exercise, and good hygiene. Both parents and children will benefit from better communication with professionals about medicines and from following the treatment plan as prescribed.

4. Work with the media to raise awareness of the need to improve prescription medicine use among children.

As a group with significant influence on health awareness, television, radio, newspapers and magazines have an opportunity to bring this issue to the public's attention. Their efforts can be directly responsible for improving the health and quality of life of American children.

5. Commission research on effective communication about medicines among health professionals, parents, children, schools and daycare centers.

Possible issues to study include how to motivate health professionals to communicate about medicines with children and parents; effective techniques for different health professional specialists in communicating with children; how to create successful parent-child-caretaker partnerships in proper medicine use; how to improve parental monitoring of children's medicine-taking; effective techniques for working constructively with teenagers to overcome psycho-social barriers to medicine use; and the role of schools in improving medicine use.

Helping America Speak Up For Children

"Talk About Prescriptions" Month, October 1989, is a good opportunity for national and community organizations to take action for improving medicine use among children and teenagers. One way of getting involved is to participate in The National Council on Patient Information and Education's new "Speak Up for Children" campaign. This national health education initiative is designed to raise awareness of the importance of communication in increasing the safe and effective use of medicines among young people.

Medicine Misuse Among Older People: New Evidence of a Significant Problem

The Inspector General of the Department of Health and Human Services recently concluded that older Americans are not receiving the full benefits modern medicines offer for improving health, prolonging life, and maintaining independence. His study confirms other evidence of this serious public health problem. Here are some excerpts from the Inspector General's review of Medicare drug utilization.

The Problem

According to Inspector General Richard Kusserow, "mismedication" of the elderly is common. Mismedication includes the prescribing of: 1) a higher dose when a lower dose would provide the same benefits with lower risks; 2) a medicine with a greater potential for adverse effects when a medicine with less likelihood for adverse effects might work as well; 3) a medication that is unnecessary, either because the patient's condition is misdiagnosed or because nondrug therapy could be substituted; and 4) multiple medications in a dangerous combination. The medicine problem among older Americans has been called "polymedicine" because of the multiple medications many older patients take.

The Inspector General's report predicts the "polymedicine" problem will worsen when the new Medicare drug benefit, passed by Congress in June of 1988, goes into effect in 1991. The drug benefit allows partial coverage of costs of prescription medications for Medicare enrollees who have exceeded a $600 deductible for medications. Historically, when the government mandates services, in this case prescription medicine use, the use of those services generally increases.

TALK ABOUT PRESCRIPTIONS MONTH

Consequences of "Mismedication of the Elderly"

According to the Inspector General, medication mistakes have the following consequences.

Adverse Drug Reactions (ADRs) that caused 243,000 older adults to be hospitalized in 1985. Although Americans age 60 and over comprise only 17% of the total U.S. population, they account for 39% of all hospitalizations and 51% of deaths from drug reactions.

Drug Induced Falls that produce 32,000 hip fractures each year.

Serious Mental Impairment, caused or worsened by medications, that affects an estimated 163,000 older Americans.

Symptoms That Mimic Parkinson's Disease for 61,000 older people due to prescribing of anti-psychotic medications.

Economic Costs for patients, families, and public and private health insurers. Estimates of the health care costs of ADR's among the elderly range from $4.5 to $7 billion per year.

In addition to the factors cited by the Inspector General, a 1987 report by NCPIE on medicine use among older Americans found that lack of effective communication between older people and their health care providers was a major contributor to medicine misuse. This includes the need for more targeted patient counseling and medication instruction as well as the need for older patients to tell professionals about other medicines they are taking and about side effects that may be drug-induced.

Working With Your Older Patients to Improve Medicine Use

How can health professionals help improve the safety and effectiveness of medicine use among older adults? The following suggestions are adopted from a National Council on Patient Information and Education report "Priorities and Approaches for Improving Prescription Medicine Use by Older Americans."

Talk to Your Older Patients and Their Caregivers About Their Prescriptions.

- Give them simple, clear, and complete instructions for use. Don't rely on the prescription label, many older people have poor eyesight or difficulty in reading.
- Provide written and/or audiovisual information to supplement and reinforce your verbal counseling.
- Designate a qualified staff member as a medication resource person to spend time going over instructions with patients and answering their questions.
- Encourage older patients to ask questions about their prescriptions, either during their visit or afterwards, by phone. This is especially important with patients from lower socioeconomic groups, who have been found to be reluctant to question the professional.
- Ask your older patients to tell you all the medicines they take, including alcohol, over-the-counter medicines and any home remedies. Many professionals ask older people to bring in all the medicines they currently take.
- Ask about smoking habits. Cigarette smoke can interfere with the effectiveness of some prescription medicines. Smokers commonly need to take more of a medicine or take it more often to get the same effect.
- Explain that older people are more susceptible to altered drug actions and that they need to report physical or mental changes that might be side effects of medications.

Factors That Lead to the Problem

1. Changes in the body with age, which alter the way older people's bodies absorb and dispose of drugs.
2. Taking multiple medications. Older people get twice as many prescriptions filled as younger people, and many regularly use more than one medicine. This increases their risk of adverse drug reactions.
3. Complex regimens, which are difficult to adhere to.
4. Multiple providers of care. Without coordination among providers, prescription orders may be duplicated or conflicting regimens may lead to adverse drug interactions.
5. Deliberate or unintentional noncompliance. Some patients decide not to have a prescription filled or to take more or less of a medicine than prescribed. Others have barriers to adherence such as physical limitations, or they simply forget a dose.

- Educate older patients and caregivers about common symptoms that may be a result of drug interactions or adverse drug reactions.
- Train older patients or caregivers to become the "coordinators" of their own care: to use one pharmacy for all their prescriptions and over-the-counter medicines; to keep records of each medicine they take; to show the records to each new provider they see.
- Counsel patients about overcoming physical barriers to taking medicines as prescribed (eg, the use of memory aids to cue administration, color coded charts to help those with poor eyesight keep track of their doses).
- Encourage patients and caregivers to work with you as a partner in determining the medicine regimen and in following treatment as prescribed.
- Discuss good safety practices such as checking the expiration date on medicines before using them, not saving medicines and self-treating with them, not sharing medicines with others, and keeping medications properly stored and out of the way of visiting grandchildren.
- Ask whether easy-open containers are preferred.

Simplify the Regimen

- Consider nondrug therapy, if appropriate.
- Begin therapy at the lowest effective dose.
- Use the fewest number of medications possible.
- Use combination medicines as appropriate.
- Look for medicines that older people can take once or twice a day rather than on a multiple dose schedule.

Monitor Therapy Carefully

- Regularly reassess the continued need for a long-term medication.
- Watch for evidence of side effects and adverse reactions.
- Review patient adherence, and suggest the use of compliance aids as needed.
- Develop pharmacy systems to track multiple medications and renewals.
- Review the effectiveness of the dosage prescribed in producing the desired results. Because drug response is highly variable in different older patients, it is important to individualize therapy based on experience.
- Share your findings with other professionals who care for the patient.

GET THE ANSWERS

ASK *these questions about your prescription medicines.*

1. What is the name of the drug and what is it supposed to do?
2. How and when do I take it—and for how long?
3. What foods, drinks, other medicines, or activities should I avoid while taking this drug?
4. Are there any side effects, and what do I do if they occur?
5. Is there any written information available about the drug?

REMEMBER *to tell your health professionals the following information when medicines are prescribed.*

1. Names of the medicines you are now taking, including nonprescription drugs.
2. Any problems you are having with your medicines.
3. The medicines to which you are allergic.

National Council on
Patient Information and Education

Meet the
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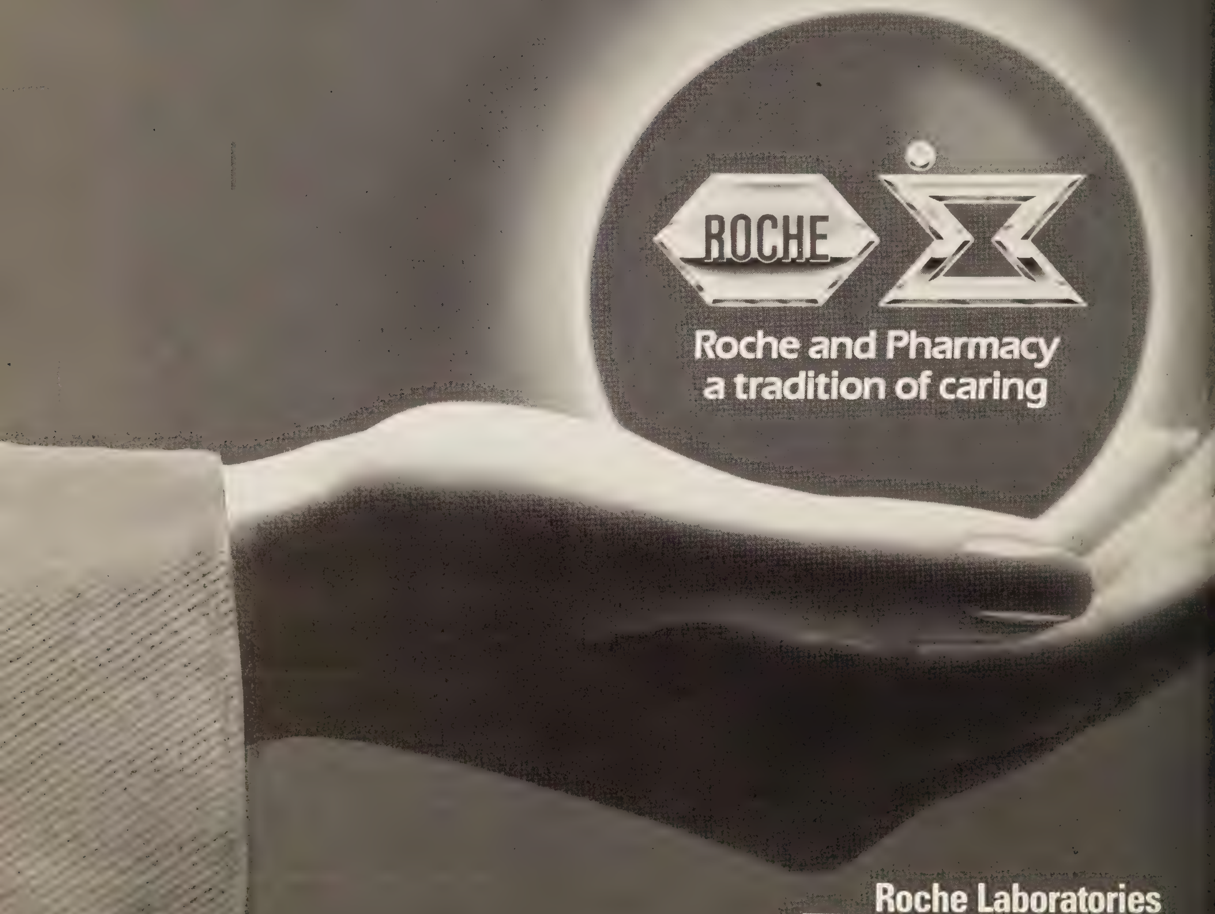
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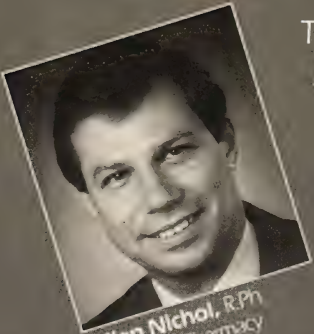

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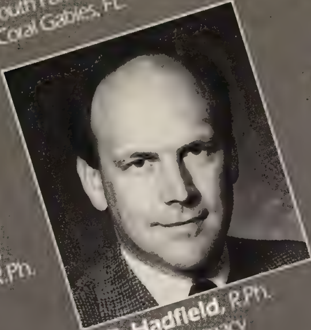

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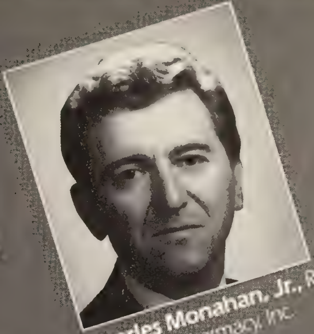

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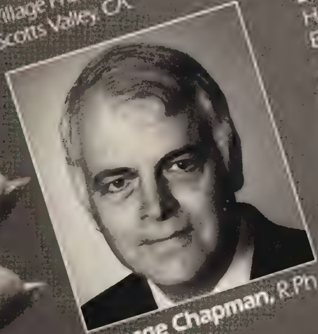

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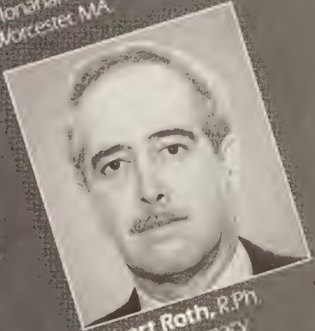

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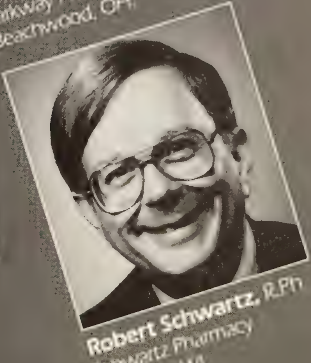

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Schwartz Pharmacy
Madison, WI

TALK ABOUT
PRESCRIPTIONS
MONTH

Tips for Health Professionals: Children and Medication Communication

Every year nearly 200 million prescriptions are written for children. About 13 million children take prescription medicines in any 2-week period. Studies show that almost half of American children do not take their medicines as prescribed, even when they have serious conditions such as cancer, renal transplantation, diabetes, and epilepsy.

How can you be sure that the medications you prescribe and dispense produce the desired results? The First step is to talk about the medicines to children and their parents, to give them the information and motivation they need to carry out their roles in therapy: filling the prescription order, taking the medicines according to instructions at the right times and in the right doses for as long as required, and giving you the feedback you need to evaluate their situation correctly.

Although parents have the primary responsibility for childrens' medicine use, it is also important to involve the child as an active participant in taking medicines as prescribed. Here are some ideas from the latest National Council on Patient Information and Education (NCPIE) report, "Children and America's Other Drug Problem," about how—and what—to communicate to children about their medicines.

1. Enable the child to have an appropriate role in following treatment.
   - Consult with the parents about your plans to present information to their child.
   - Talk directly to the child in addition to communicating with the parent. The parent will also hear the information you offer the child.
   - Explain the benefits to the child of taking a prescribed medicine.
   - Explain any medical terms you use in words the child can understand.
   - Encourage the child to ask questions.
   - Ask the child to repeat your instructions to show that he or she understands.
   - Encourage the child to follow through and take the medicines as prescribed.
   - Praise the child for active participation and taking responsibility for his health.
   - Assist the child and his parents in deciding which roles each will play in medicine use (eg, who will remember to take the medicine, who will administer it, who will keep the medicine record, who will make decisions about medicine use?). Family confusion over roles and responsibilities can be a major cause of nonadherence.
   - Emphasize to the child and parents that parents should continue to supervise the child's medicine use appropriately. While it is valuable to involve the child in medicine use, it is critical not to lose parental supervision—at all ages.
2. Communicate about medicines in a warm and caring way.
   - Be friendly rather than businesslike.
   - Avoid medical jargon.
   - Try not to appear rushed as you answer questions and help patients identify and overcome barriers to adherence. If a problem takes too much time to resolve now, have the parent schedule another visit.
   - Spend a little time talking about non-medical topics.
   - Make your intructions simple and specific.
3. Talk with the child according to his or her cognitive level. Cognitive development theory suggests that children's ability to conceptualize about health and illness progresses chronologically through stages, each of which serves as a necessary stepping stone to the next. The four stages of development include:
   - Sensory-motor (birth to age 2). The child experiences his environment in terms of his own physical sensations.
   - Pre-operational (ages 2 to 7). Children can understand words and symbols, but cognition is egocentric and empirical rather than logical. They can only focus on one idea at a time. Health concepts are very general and tend to be superstitious. Children often see illness as a punishment for being bad and can't describe what it means to be "healthy." At this stage it is appropriate to talk to children directly about medicines and treatment instructions.
   - Concrete operational (ages 7 to 11). Children begin to use elementary logic. They can focus on several concepts simultaneously. They can understand health ideas such as a disease being caused by germs. At this stage it is useful to get the child's consent to the treat-

Continued on page 21. . . .

You not only have the need to know. You have the right to know.

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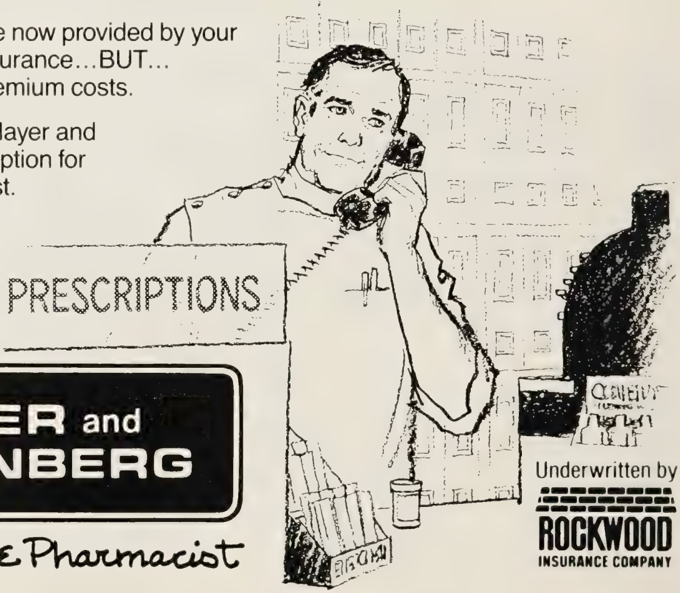

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ment plan you propose. This kind of involvement produces a greater commitment to following treatment.

  - Formal operational (ages 11 to adult). Children are capable of abstract thought, can see alternative possibilities in a situation, and can interpret based on their own reasoning. At this age involving children in determining some of the details of the treatment regimen can enhance adherence. It is also useful to discuss directly the importance of compliance and good medicine safety practices, because many children in this stage are given considerable autonomy in taking their medicines.

4. Help overcome refusal to take medicines.
    - Check for objectionable side effects and investigate adjusting the dosage or changing the medication.
    - Explore fears about the medicine.
    - Talk to children to make sure their "refusal" is not a covert expression of parental resistance. Discuss attitudes about medicine use with both children and parents.

Reaching Out With Medication Information

A 1986 survey conducted by the U.S. Food and Drug Administration found that about one in every three Americans is receiving no information from their health professionals about the medicines they are prescribed before they take them. Yet these patients are the least likely to ask questions or recognize the importance of obtaining information and thorough instructions for use. Physicians, pharmacists, nurses, dentists, and other health professionals can help fill this information gap by reaching out and providing information spontaneously.

The following are suggestions compiled by the National Council on Patient Information and Education (NCPIE), about effective techniques for reaching out and opening the lines of communication.

- Show concern for and interest in the patient using both verbal and nonverbal communication. Patients are more likely to accept your instructions when they feel that you care about them.
- Listen actively to your patients. This may mean talking less than the patient, paying good attention to what the patient says, and responding with a restatement of the patients' comments to show understanding.
- Work with the patient to identify and solve potential problems. Without probing for barriers, unrecognized obstacles may compromise the patient's willingness or ability to follow medication treatment.
- Use language the patient can understand. Some patients do not find technical terms a barrier to communication, but many others do. You need to assess each patient's language needs.
- Present facts in a logical, organized manner. People are most likely to remember the information you present first and last; make sure these are the most important points.
- Summarize key information after you present it.
- Ask the patient to restate your instructions to ensure comprehension.
- Encourage questions. Let patients know that there are no "dumb questions," and that they should feel free to ask about anything they don't understand. Many patients may be in pain or overwhelmed by a diagnosis while they are initially with you. Let them know that they should review what you've told them when they get home and call if questions occur to them then. Suggest that patients write down questions prior to coming to see you.
- Provide written information. Studies show that patients are most likely to adhere to treatment when professionals offer written information to supplement their verbal counseling.

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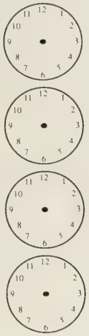
Medicine Record

To help you remember to give all your child's doses at the right times, fill in clock face with time of dose and check off each dose as you give it!

WEEK #1 MON. TUES. WED. THUR. FRI. SAT. SUN



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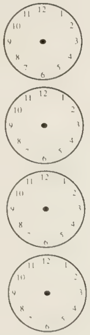

Name of Medicine

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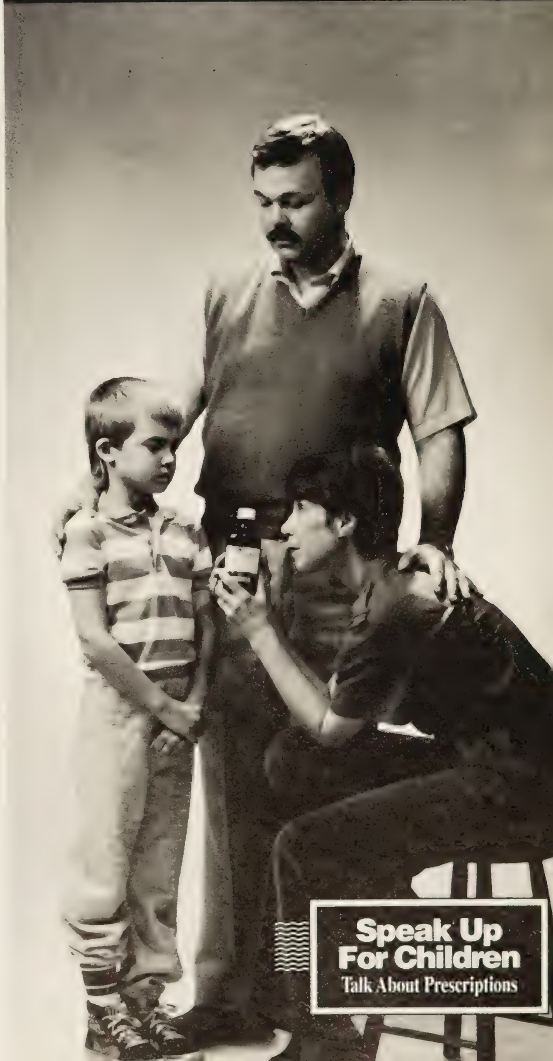
A Parent's Guide For Medicine Use by Children


Speak Up For Children
Talk About Prescriptions

Speak Up For Children

Talk About Prescriptions

Medicines can help your children feel better and stay active. Sometimes they even save lives.

To work the way they should, medicines must be used properly. When we make mistakes in the way we give medicines, children don't get well. Some mistakes cause problems that can put your child's health -- and life -- at risk. The common mistakes that hurt children's health include:

- Stopping a medicine too soon or too suddenly.
- Not giving enough of a medicine (forgetting or skipping doses and giving them at the wrong times).
- Letting a child refuse to take a medicine (or deciding on your own not to follow the doctor's advice).
- Giving too much of a medicine (giving larger doses or giving them more often than advised).

How can you be sure that you do what's best for your child? The first step is to speak up. Talk to your health professionals, your children, and the others who take care of your children about every medicine they take.

Talk to Your Health Professionals

- Discuss the decision to begin or continue use of any medicine. Find out about non-drug approaches that may be used along with medicines.
- Ask your doctor to explain the benefits and the potential risks of medicines he or she prescribes for your child.
- Tell your doctor or pharmacist about other medicines your child is taking, including over-the-counter medicines. This can help prevent drug interactions.
- Ask doctors and pharmacists the 5 questions that appear on this brochure. Take the brochure along when you visit the doctor's office or pharmacy. Use the space provided to write down the answers.
- Never stop, or adjust, the dosage of your child's medicine without consulting the doctor.
- Monitor and report on your child's response to the medicine. If you think it is causing side effects, let the doctor know. Don't be afraid of "bothering" him or her. Doctors need feedback to give the best treatment.
- Call the doctor or pharmacist if you have other questions later on. Don't "guess" when it comes to medicines

Talk to Your Child

- Teach your children that proper use of medicines, is a key to good health, just like eating right or brushing your teeth.
- Explain the difference between legitimate medicines and illegal drugs. Use only the word "medicines" to talk about prescriptions and over-the-counter medicines. Use the term "drugs" to refer to illegal substances.
- Encourage your children to ask questions of the doctor and pharmacist about the medicines they will be taking. Show them how by your example.
- Decide together which responsibilities you and your child will have in following the treatment. A younger child might help you remember each dose; a teenager might take the lead, with you monitoring and providing back up.
- Get your child's help in solving problems that make it hard to follow treatment, such as remembering medicine in a busy schedule, taking medicines in school, and coping with side effects.

Talk to The Others Who Care For Your Children

The Other Parent. Both parents and step-parents should be involved in helping the child take medicine. Share information you get from the health professional. Explain instructions. Clarify the roles each of you will play.

Grandparents, Day Care Helpers, Babysitters. Explain the medicine schedule and treatment details to all those who give your child medicine in your absence. Follow up to be sure your instructions were carried out.

Schools and Teachers. Tell school personnel if your child is taking a long-term medicine or if a dose is needed during school. Involve the teacher or school nurse in watching for side effects, problems in taking medicines, or other problems.

Get The Answers To These Questions From Your Doctor Or Pharmacist

Write The Answers In The Space Provided As A Reference For You And Others Who Care For Your Child.

1. What is the name of the medicine and what is it supposed to do?

2. How and when do I give the medicine and for how long?

3. What food, beverages, other medicines, or activities should the child avoid while taking the medicine?

4. Are there any side effects, and what do I do if they occur?

5. Is there any written information available about the medicine?

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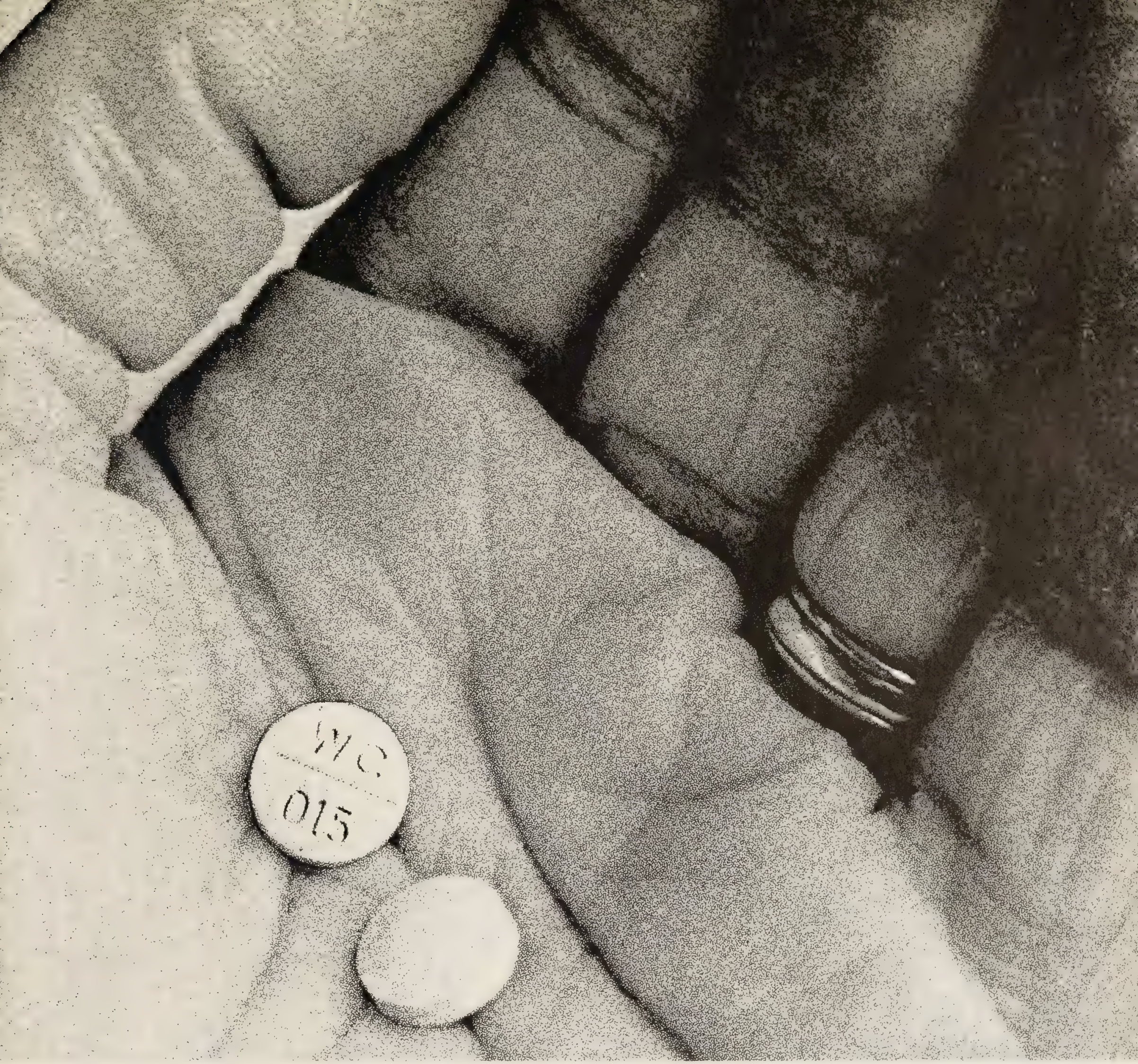

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TALK ABOUT
PRESCRIPTIONS

SPEAK UP AMERICA

Whenever medicines are prescribed, tell your health professionals:

1. the medicines you are taking, including nonprescription medicines;
2. any problems you are having with your medicines;
3. medicines to which you are allergic;
4. if you are, or think you might be, pregnant.

NATIONAL
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PATIENT
INFORMATION AND
EDUCATION

Things You Should Know FOR YOUR GOOD HEALTH

Don’t Forget To Ask!

Poor communication between older patients and their health care providers — doctors, pharmacists, and nurses — is a key factor in drug misuse. Older people are at particular risk for prescription drug misuse because people over 65 fill twice as many prescriptions as do younger people. And people over 60 experience 40 percent of all adverse drug reactions. In fact, nearly 25 percent of hospital admissions of older people are due to problems with taking prescriptions incorrectly. This means that if you are in the elder population, you should be talking more, much more with your pharmacist and physician.

Questions you should ask your pharmacist about your prescription medication include: What is the name of my medication? For what illness might my physician have prescribed this medication for me? How often should I take this medication? Will the food I eat interfere in any way with the effectiveness of this medication? Should I take the medication before, after, or between meals? What kind of effects will I notice when I begin to take this medication? Will these effects diminish or go away after I have taken this medication for a while? Will this medication make me drowsy enough to be concerned about driving or operating other dangerous machinery?

If you receive answers to all of these questions, you will have gathered a lot of information. With so much to know about medication, it is easy to get confused. This confusion is compounded if you are taking more than one medication at a time, as is often the case with older people. If keeping all of this information organized seems too much for you to handle, ask your pharmacist for explicit written instructions. Patient instruction leaflets exist for many medications. If a leaflet is not available for your medication, ask your pharmacist to prepare this information in an easy to read type-written format. (This may cost a few extra dollars but the aggravation you save and the problems you avoid will make it money well spent.)

Take advantage of your community’s medication information resources by talking with your pharmacist and other health professionals.
It’s For Your Good Health.

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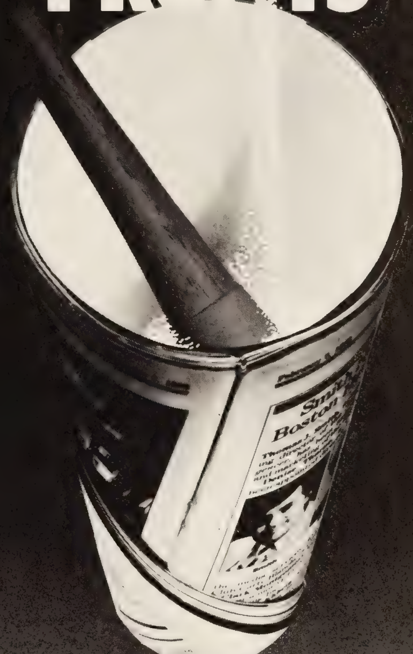

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Jim Dickinson

When generics are NOT equal. The generic drug industry has been very successful in conveying the clear message that their products are "equal" (read "therapeutically equivalent") to branded drugs.

Aided by the willing believers in Congress, state legislatures, all kinds of third-party programs, chain and mail-order drug companies, and such consumer organizations as the AARP, this simple theme has been adopted almost everywhere.

The U.S. Food and Drug Administration for over a decade has watched benignly as generic substitution has spread on the reassurance that FDA itself "guarantees" the interchangeability of brand and generic.

Now it's time to rain on the parade. In March, FDA publicly admitted on nationwide television (NBC's "Today" show) that the equality story has been carried too far.

I will let the "Today" show itself tell the story.

Art Ulene: Good morning, Jane. It's a story that surprised me—generic drugs are supposed to be equal to the brand drugs. At least, that's what I thought, until I read a letter to the contrary in one of my medical journals. I'll let the doctor who wrote the letter explain it for himself.

Rudi Ansbacher, MD, U. of Mich.: About two years ago I had three patients who came to me with complaints that the medication they were taking was no longer effective. It was interesting, because I'd placed them on conjugated estrogens, brand name. When I questioned the three of them, they said they had gone to the drug store and received a generic.

Janice Corlew: I went to the drug store to get a refill on my prescription, and apparently the insurance company would not pay for their portion of the drug Premarin. They insisted that we substitute a generic drug. I had read reports about generic drugs and how they were supposed to be the same as the brand name drugs —so I took the generic with no questions. Within just several days, it didn't take long, I began getting the headaches again . . .

Ansbacher: So I decided to check this out. I asked the patients to bring the pills in, which they did. I switched them back to the brand-name conjugated estrogens, and found out that the pills, when they were evaluated, were below the standard of what they should have had in them.

Corlew: He wrote me another prescription, Dispense As Written, and insisted that it be Premarin—told me to insist that it be Premarin, which I did. Within just several days after I started taking the Premarin again, I could tell the difference.

Ulene: Janice Corlew got two pills with the same chemical name, but with different effects. We asked the FDA to explain how that could happen. We were told that she had been given a "B"-rated generic. Why would the FDA allow a generic pill to be sold if it is not equivalent to the brand drug?

Peter H. Rheinstein, MD, JD (FDA): "A"-rated drugs have presented a human study to show that the active ingredient from the generic product gets into the bloodstream at the same rate and to the same extent as the brand-name product. The "B"-rated products generally have either not presented that sort of study—that's a rating of "BP"—or there's in fact documented evidence that they're not bioequivalent.

Ulene: How do you tell if the generic drug you're getting is an "A" or a "B"? The answer to that question is in this book. Drug experts refer to it as the "Orange Book," but few of the people prescribing and dispensing drugs are familiar with it.

Barry Pascal, pharmacist: I don't believe many pharmacists know what an "Orange Book" is. I don't believe many physicians know what an "Orange Book" is. We do not have an "Orange Book." We have one on order.

Ulene: Our next question was—What should Janice Corlew do to keep this from happening again?

Rheinstein: If she wants assurance that the drug she takes is bioequivalent to the one she had been taking, that she won't have to adjust the dosage, she needs to ask the pharmacist, "Do you have an 'A'-rated generic?" With respect to Premarin, the pharmacist is going to answer, "No."

Ansbacher: In the case of conjugated estrogens at this point in time, I write Dispense As Written on every prescription that I write.

Corlew: I hope that by bringing this to the attention of the public, someone else doesn't have to go through the misery that I went through. The only thing I can say to them is, everybody has to make the choice. I have made the choice never to take another generic drug as long as I live!

Ulene: About 20% of the generic drugs on the market today have not been designated as therapeutically equivalent to the brand names they are meant to replace. Keep that in mind the next time you get a prescription filled with a generic drug. If it's not on the "A" list, I'd ask for a brand name instead.

FOOTNOTE: The FDA "Orange Book" is now available from USP as the third volume in its "Dispensing Information" series (301-881-0666).

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Continuing Education Quiz

The Maryland Pharmacist OCTOBER 1989

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by December 31, 1989. A continuing education certificate for one contact credit) will be mailed to you within 30 days. Please type or print clearly.

Name ______________________________

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Is this program used to meet your mandatory CE? [ ] Yes [ ] No

Did this article achieve its stated objectives? [ ] Yes [ ] No

How long did it take you to complete the program? __________ minutes

New Drugs 1988-89

1. The drug that causes wide swings in blood pressure between peak and trough levels is:
   a. ethanolamine.
   b. carteolol.
   c. nimodipine.
   d. nicardipine.

2. Which of the following is the most appropriate advice to convey to a patient receiving a prescription for Cytotec?
   a. Do not take this drug if you are pregnant.
   b. Do not take this drug if you are over 65 years of age.
   c. Avoid prolonged exposure to sunlight.
   d. Avoid taking Cytotec concurrently with NSAIDs.

3. The new drug that was approved for concurrent administration with leuprolide:
   a. reduces renal damage caused by leuprolide.
   b. enhances the therapeutic response of leuprolide.
   c. protects against leuprolide-induced GI erosions.
   d. reduces skin damage by leuprolide plus UV light.

4. Octreotide is a long-acting analog of which of the following substances?
   a. Gastrin
   b. Prostaglandins
   c. Somatostatin
   d. Serotonin

5. Which of the following drugs is classed as a dopamine agonist?
   a. Permax
   b. Cardene
   c. Eulexin
   d. Ifex

6. Patients on diclofenac should be tested periodically for:
   a. peptic ulcer disease.
   b. open-angle glaucoma.
   c. liver function.
   d. cataract formation.

7. A person who excretes abnormally high amounts of cystine would be treated most appropriately with:
   a. Permax.
   b. Sandostatin.
   c. Ethamolin.
   d. Thiola.

8. Which of the following drugs is in Phase III clinical trial for treatment of Alzheimer's disease?
   a. Pergolide
   b. Nimodipine
   c. Flutamide
   d. Carteolol

9. Toxicity to acreolin is best reduced by which of the following drugs?
   a. Diclofenac
   b. Misoprostol
   c. Mesnex
   d. Nizatidine

10. A resident who asks for information on a new drug that treats symptoms of VIPomas should be told about:
    a. exametazine.
    b. tiopronin.
    c. ifosphamide.
    d. octreotide.

Classified

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

PHARMACY RX ITEMS, broken containers, fast and medium movers for sale at reduced prices. Contact Preston Pharmacy at (301) 673-2318. Pharmacist closing store.

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PHARMACISTS REHABILITATION COMMITTEE HOTLINE is (301) 727-0746.

ATTENTION—HIRING! Government jobs—your area. Many immediate openings without waiting list or test. $17,840–$69,485. Call 1-602-838-8885. Extension 9494.

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Hats Off To Their Hands-On Achievements.

We salute the dedication and the "can-do" spirit of these four young students, members of Upjohn's 16th Annual Internship Program, co-sponsored by the National Pharmaceutical Council and the American Pharmaceutical Association Academy of Students of Pharmacy.

For ten weeks last summer, they learned from the best possible teacher: Experience. Working side by side with top Upjohn professionals in the key areas of sales, marketing, research, and production, they experienced firsthand the ways in which theory is put into practice in the real world of the pharmaceutical industry. It wasn't easy, but what they learned from this intensive, hands-on training will serve them well wherever their careers in pharmacy take them.

The Internship Program is one example of Upjohn's continuing commitment to pharmacy. We salute these student leaders for *their* commitment to the future of their chosen profession, and wish them well in the years ahead.

Upjohn

Pictured left to right: David R. Karls, University of Wisconsin-Madison; Melissa A. Edmiston, Samford University; Carole A. Wilkins, Wayne State University; Gary C. Paul, University of Iowa

The Maryland Pharmacist

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Pharmacy Services: Some Thoughts on Reimbursement and Competition

The great debate about whether the pharmacy profession provides a service or a product is gradually being settled—pharmacy is a little of both.

Unfortunately, services cost money. It is sorely disheartening to hear that pharmacists must curtail service to some patients because of inadequate third-party reimbursement.

One MPhA member has shared with us his letter campaign to third-parties and to patients:

> ''Should you survey your enrollees, you will find that our pharmacies provide quality community services in a professional environment, while adhering to the guidelines of your program.''
>
> ''The point of this letter is to have you address the question of pharmacy reimbursement. Dispensing fees have remained static for years, while all operating costs at the pharmacy level have increased. Fixed dispensing fees, without annual adjustments or indexing to inflationary changes, do not reflect market realities.

Maryland pharmacists need to sit down and truly assess the financial impact that each new third-party program or new contract has on his or her business and the provision of services to patients. MPhA has materials and professional contacts to help you determine your cost-of-dispensing to do this assessment.

Maryland pharmacists need to start standing up and asking for fee increases and for reimbursement for services above and beyond the dispensing of a prescription.

Finally, we must take our cause to those most impacted by the insidious practices of unfair and insufficient reimbursement policies—our patients. They must be told what their insurance companies are doing to us.

Nathaniel Futeral, P.D.

President

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Advising Consumers on OTC Contraceptive Products

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. explain the correct use of OTC contraceptive products; and
2. discuss their adverse effects and overall usefulness.

Objectives

At the conclusion of this lesson, participants should be able to:

1. demonstrate knowledge of the advantages and disadvantages of each type of OTC contraceptive;
2. exhibit an understanding of how OTC contraceptives must be used in order to maximize their effectiveness; and
3. choose from a list, specific points of patient advice to convey to consumers.

Gossel

Wuest

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from

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Millions of American men and women rely on contraceptives to protect against unwanted pregnancies and sexually-transmitted diseases (STDs). Though the number of females using oral contraceptives is increasing, it is reported that the actual percentage of women using them is decreasing. Information available via the oral contraceptive patient package insert, and their concern about blood clot formation and threat of hypertension have led to their decline.

IUD usage has also lessened. The physical damage caused by IUDs in some women and the adverse publicity surrounding the Dalkon Shield have led to their decreased popularity.

Because of these factors, the use of condoms and spermicides has increased. Recently, condom use has been further advanced due to concern about AIDS, and the removal of restrictions against advertising them.

Condoms

Today, more than two-thirds of all condoms are used in industrialized countries. They are not as popular a means of personal hygiene or contraception in underdeveloped countries.

Heightened awareness among medical personnel and consumers of the high rates of sexually transmitted diseases (STDs) is a reason why condoms are being used more in this country. Another concern is the increasing number of unwanted pregnancies both out of wedlock and with teenage girls, which has stirred a movement of pregnancy-prevention clinics nationwide.

No doubt the successful sales promotion programs of condom manufacturers in magazines and on television, lifting of restrictions against their display in many jurisdictions, and innovations in packaging which promise consumers increased sensitivity, are also contributing to this burgeoning market.

Regardless of what forces have awakened Americans to using condoms more often, they represent the most reliable of all OTC birth control measures (Table 1). The current trend toward increased use of condoms will undoubtedly continue.

Condom Use Through the Years

The derivation of the word "condom" may be from the Latin stem "condus" which means receptacle. Items similar to today's modern condoms have been used to prevent STDs for approximately 400 years, and as contraceptives for at least 250 years. Rubber condoms comprise the overwhelming bulk of the condom industry.

Until the mid-1920s, condom sales were restricted primarily to outlets such as pool halls, gas stations, and barber shops. Rarely were they sold in pharmacies, even though they were labeled "for the prevention of

TABLE 1

Pregnancy Rates of Various Contraceptive Methods

Method of Contraception	Pregnancies/100 Women-Years
Oral Contraceptives	
≥35 mmg ethinyl estradiol	<1
≥50 mcg mestranol	<1
≤35 mcg ethinyl estradiol	>1
Progestin only	3
Mechanical/Chemical	
IUD	<1–3
Vaginal sponge	9–16
Diaphragm (with cream or jelly)	2–20
Condoms	3–20
Aerosol Foams	2–25
Gels and Creams	4–36
Rhythm (all types)	<1–47
Withdrawal	9–25
No contraception	60–80

Facts and Comparisons, JB Lippincott, St Louis MO, p 535, 1988

disease only." They were stocked in drawers out of sight to the public.

But in the mid-1920s, Merle Youngs, a sundry salesman who called on drug stores, started a condom manufacturing company. He demanded strict standards of quality, worked closely with pharmacists, provided them with a decent return on investment, and assured them that his products would only be sold in pharmacies. It worked.

Different Forms of Condoms

There are basic differences between the two major types of condoms in use today — latex and animal skins (lambskin, lamb intestine). Animal-derived products transmit body heat to greater extent than latex. They therefore provide enhanced sensitivity. Latex condoms are more elastic and afford a snugger fit. Since animal intestines are not elastic, lambskin condoms may slip off during penile withdrawal after coitus. They are also considerably more expensive than latex condoms. This is due to limited availability of their source, slaughtered animals.

Condom Effectiveness

Theoretically, a condom should be 100 percent effective as a contraceptive. However, there is a possibility that a condom may break or leak, or not be used properly, resulting in pregnancy.

Studies conducted in the United Kingdom concluded that the pregnancy rate with condom usage was 1.4 per 100 couple-years. In other words, when couples used condoms for contraception for a year, an average of 1.4 pregnancies occurred in every 100 couples. Other reports reveal an overall pregnancy rate of 0.5 to 1 per 100 couple-years.

Pregnancy rate is highly dependent on consistency of condom use. In the studies cited above, couples who used condoms inconsistently (i.e., during what they considered "unsafe" days) experienced pregnancy rates as high as 6.8 per 100 couple-years. Regardless, condoms are the most effective means of contraception available without a prescription or surgery.

Arguments For and Against Condom Use for Contraception

Arguments in favor of condoms stress that they help prevent disease and cervical cancer, and overcome infertility in some women. Arguments against condoms cite inconvenience and reduced tactile sensitivity. These and other factors are summarized in Table 2.

Sexually Transmitted Diseases. Condoms offer the only effective means to guard against STDs, other than abstinence. A retrospective study of 246 sexually active soldiers who served in Vietnam revealed the following statistics. None of 55 soldiers who always used condoms contracted an STD. This contrasted to 35 percent of 191 soldiers who did not use condoms and became infected with an STD (mostly gonorrhea or chancroid). Occasional use of condoms or washing after intercourse did not make a significant difference in the outcome.

Genital herpes is one of the most rapidly developing STDs in the U.S. It has been suggested that the herpes virus can pass through pores of condom membranes, but this is unlikely. The causative organism, Herpes simplex virus, has a diameter of 0.1 micron (one ten-thousandth of a millimeter). By comparison, water and air molecules are about 1000 times smaller than the herpes virus. Since good quality condoms are watertight and airtight, they undoubtedly protect against herpes virus infection. This protection against transmission with latex, but not lambskin con-

TABLE 2

Advantages and Disadvantages of Condoms

Advantages

- Inexpensive
- Easily obtained
- Safe and effective
- No after-effects or toxicity
- Protect both men and women against STDs
- Used without medical supervision
- Good for people who engage in sexual acts infrequently

Disadvantages

- Messy to use
- May be difficult to dispose of
- Cause decreased sensitivity
- Many men do not use them properly
- May be associated with psychological problems, so cause reduced pleasure

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7. ARE YOU INTERESTED IN A TOTAL PROGRAM THAT WILL SOLVE ANY OR ALL OF THE ABOVE?

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doms, has also been shown for the HIV (AIDS virus).

Cervical Cancer. It is thought that cervical cancer is initiated or promoted by a factor transmitted by sexual activity. The agent may be a strain of herpes virus since it is often found in the cervical tissue of patients with cancer. Studies show that women who rely on barrier methods (including condoms) for at least five years have a lower rate of cervical cancer than their sexually active counterparts who do not use them.

Infertility. Condoms are useful to treat some women who are infertile because they are allergic to sperm. Up to 30 percent of all unexplained infertility is believed to be related to antibodies produced by the female when sperm (a foreign protein) comes into contact with cervical tissue. Using a condom allows antibody titres to decrease.

Beneficial results from one study showed that 15 of 19 women with unexplained infertility had high antibody titres to sperm. Five of these women's partners subsequently used condoms for 2 to 6 months, then timed unprotected intercourse with ovulation. All five women showed a significant decrease in sperm antibody levels, and three became pregnant.

The two biggest disadvantages of condom use are inconvenience and decreased sensitivity. To be fully effective, condoms must be kept at easy access during sexual activity. Those who have limited personal privacy may be unable to readily store or dispose of them afterward.

An investigation of nearly 2000 men and women reported 63 percent complained of decreased sensitivity to coitus. This may actually be an advantage to other people. In the same study, 38 percent of men and 14 percent of women reported that condoms prolonged coitus, and hence, overall pleasure. The sensitivity issue is obviously psychological and difficult to measure.

Proper Use of Condoms

To be effective, condoms should be applied before genital entry. There may be sperm present in the pre-ejaculatory fluid, although studies have not confirmed the presence of motile sperm in this fluid if the man has urinated since his last ejaculation. When condoms are used for protection against disease, they must be applied before contact and worn for the entire duration of sexual play. A single, momentary contact with an infected area can transfer pathogens.

Leaving an air space in the closed end of a condom is not absolutely necessary. Some believe this space is needed to contain the ejaculate and decrease the chance of breaking due to the force of ejaculation stretching the condom end. But condoms are sufficiently strong to withstand this pressure and quantity of ejaculate.

Withdrawal immediately following ejaculation is not necessary as long as the condom remains firm around the penis. If the erection is lost prior to withdrawal, the condom should be held in place with the fingers during withdrawal.

Spermicides

Vaginally applied substances have also been long used for contraception. Egyptian papri dated four thousand years ago described vaginal preparations made from honey and sodium carbonate. Various other concoctions through the ages have also been recommended, including quinine, lactic acid, boric acid, burnt alum, mercurial salts, even animal dung (most specifically from crocodiles and elephants!). Since some of these early folklore remedies were strongly acidic or alkaline and extremes in pH immobilize sperm, many may have been effective.

Surfactant Spermicides

Introduced in the 1950s, surfactant spermicides were forerunners of substances in current use. "Nonionic" surfactants (i.e., they do not ionize in solution, and thus, are less readily involved in chemical reactions) are the principle ingredients used in most spermicidal products (Table 3). They are both effective and safe chemicals to use for vaginal contraception.

Effectiveness is greatly dependent on how they are used, and on the

TABLE 3

Representative Examples of OTC Spermicidal Products

Active Ingredient	Product	Concentration	Dosage Form
Nonoxynol 9	Because	8%	Foam
	Conceptrol	4%	Gel
		5%	Cream
	Delfen	12.5%	Foam
	Emko	8%	Foam
	Encare	2.27%	Suppository
	Excita Extra	5.6%	Condom
	Gynol II	2%	Jelly
	Intercept	100 mg	Suppository
	Koromex	3%	Jelly
		12.5%	Foam
		5.6%	Condom
	Koromex Crystal Clear	2%	Jelly
	Ortho-Cream	2%	Cream
	Ortho-Gynol	1%	Jelly
	Ramses	5%	Jelly
	Ramses Extra	5.6%	Condom
	Semicid	100 mg	Suppository
	Sheik Elite	5.6%	Condom
	Shur-Seal Gel	2%	Jelly
	Today	1 gm	Sponge
Octoxynol 9	Koromex	3%	Cream

specific product form. To illustrate, aerosol foams are more effective than creams, gels and suppositories. Aerosol delivery systems allow for more favorable placement of the product. Suppositories afford special problems relating to proper alignment within the vagina, the lagtime required for melting and releasing the active ingredient, and the duration of spermicidal action.

Spermicides should be used before the initial and each subsequent sexual act. Women should not douche for at least 8 hours after coitus.

How Do Spermicidal Agents Act?

Spermicidal drugs act by one of two actions. They may provide a physical barrier against sperm entry through the cervical opening into the uterus. Or, they may directly kill or immobilize sperm. They are more effective when used with a diaphragm, than when used alone.

Nonionic surfactants appear to exert spermicidal activity directly on the constituents of lipid-containing membranes of sperm. This results in their loss of motility and ability to metabolize fructose, altered permeability, and the woman's immune system being better able to detect and destroy the sperm. Sperm requires fructose; interfering with its usage greatly reduces their survival.

Are Spermicides Safe?

Although many spermicidal substances have been available through the years, at present only three are proven to be both safe and effective. These are nonoxynol 9, octoxynol 9, and menfegol. Menfegol is not currently used in the U.S.

Spermicides have long been the subject of controversy because of their implication in causing birth defects. Nonoxynol 9 and octoxynol 9 are both absorbed through the vaginal mucosa into the systemic circulation of laboratory animals. However, most animal studies have failed to report serious effects. Absorption has not been established in humans, mainly because there is no analytical test to measure their presence in the blood. Based on animal studies, though, the possibility exists since nonionic detergents pass through most biologic membranes.

A study was undertaken to assess whether nonoxynol 9 causes systemic effects following vaginal application. Premenopausal women ages 18 to 39 were randomly assigned to one of three groups. One group received 2.5 gm of a 5 percent nonoxynol 9 vaginal cream preparation daily for two weeks. A control group received 2.5 gm of the cream base alone, and the third received no treatment. Fasting blood samples were obtained from each subject before treatment, and again on the eighth and fifteenth day following treatment. There was no difference in the measured parameters between pre- and post-treatment periods in any group. The study concluded that there are no systemic effects from vaginal application of a 5 percent nonoxynol 9 cream preparation.

Decades of use have yet to identify significant adverse systemic effects. Minor topical afflictions include burning or stinging of the vagina or penis. Topical irritation varies with different products. This could be due as much to the vehicle, inert ingredients, frequency of intercourse, or presence of infection as to the spermicide itself.

Contraceptive Sponge

The contraceptive sponge consists of a disposable polyurethane sponge shaped like a button mushroom. It is impregnated with 1 gm nonoxynol 9. The sponge seems to be an ideal contraceptive. It physically blocks the entry of sperm, absorbs it, and kills it. Unlike IUDs, the sponge is intended to be used only when needed. The user can engage in coitus multiple times during a 24-hour period without any additional preparation. Moreover, the sponge does not require fitting or special intervention by a physician.

The product's manufacturer reports that no significant adverse effects appeared during more than five years of clinical trials in countries around the world. The sponge has not shown a potentiating action on *Staphylococcus aureus*, the microbial cause of toxic shock syndrome, which can develop with tampon use.

Consumer Advice

Directions for using any contraceptive must be closely followed. These are likely to be understood, but pharmacists may want to assure that consumers do indeed know how to use them.

A recent note published in the pharmacy literature revealed that at least one new mother did not understand labeled instructions. She had used a contraceptive jelly prior to conceiving, but had spread it on her breakfast toast. Her remark was, "That 'jelly' was to be used on bread!"

Rash and/or itching, while uncommon, have been reported. They are usually due to chemicals used in the manufacturing process, or to the lubricant, if present. Since the composition of various condoms differ, switching to an alternate product may alleviate the problem. If irritation persists after changing brands, it may be indicative of an STD, and the individual should be urged to see a physician.

Consumers who are concerned about condom breakage or leakage should be reassured that those which are supplied by reputable manufacturers meet rigid test standards. The chance for obtaining a defective product is minimal.

Spermicidal agents can also be sensitizing. Consumers who complain of continued irritation should be advised to check with their physician or choose a different method of contraception. Since there is a possibility that they may cause birth defects, it is best not to use them if there is a chance that pregnancy has occurred. It should be evident, but may not be completely understood by all potential users, that spermicides do not protect against sexually transmitted diseases.

Various studies have recently shown that in spite of national attention to the health benefits of using condoms, there is still a large degree of ignorance among many people. This is especially true among teenagers who may view the problem of STDs as being one of sexually promiscuous "older" individuals. All consumers, regardless of age, should be counseled whenever appropriate.

Pharmacy Services: Preliminary Results of a Statewide Survey

Kathleen Gondek, M.S. and Peter P. Lamy, Ph.D., Sc.D.

Introduction

The fastest growing segment of the population is those over the age of 85. Their desire, as well as that of their "younger" cohorts, to remain as independent as possible has created a large group of caregivers. Caregivers are assisting the elderly in managing their problems, often without the appropriate information and knowledge of resources available. It is estimated caregivers will spend more years caring for an elderly parent than they did raising their children. Medication management is a concern for many caregivers. In a survey conducted by the American Association of Retired Persons, 45% of caregivers desired more information about medications.

The Maryland Caregiver program conducted by the Center For the Study of Pharmacy and Therapeutics for the Elderly, sponsored by the Governor's Office of Justice Assistance, offers caregiver workshops in medication management throughout Maryland. *The Caregiver's Guide to Medication Management* provides information regarding medications, addresses home safety, disease prevention measures, agencies where help is available, and legal issues.

A focus group of caregivers was developed to evaluate the *Guide*. The group addressed several issues: understandability, length, completeness, questionnaires, disease topics, and some editorial issues. One of the suggestions of the focus group was to survey all Baltimore city pharmacies to determine the services they provide. The pharmacy list could then be made available to the participants of the caregiver workshops.

The opportunity to make the public aware that pharmacists did more than count pills could not be overlooked.

Methodology

Initially, two hundred pharmacies in Baltimore city were surveyed. Three months later all pharmacies in Maryland were surveyed, totalling 929 pharmacies. The pharmacy list was obtained from the Maryland Board of Pharmacy, which included all licensed pharmacies. Hospital pharmacies were not included in the survey. However, Health Maintenance Organization (HMO) pharmacies were surveyed. Many people in the community have their prescriptions filled at these sites and would benefit from knowing the services provided. The one-page survey (Appendix A) used a simple check format.

Results

The results presented here are preliminary and believed to be of interest to practitioners. Forty-three percent of pharmacies in Maryland responded to the survey. Sixty-three percent of respondents were independent pharmacies, 32% were chains, less than one percent were HMOs, and less than one percent were home care pharmacies (specializing in intravenous therapy). The number of services provided ranged from zero to 18, with a mean of 5.4, and a mode of three.

Senior discount, provided by 77.7% of pharmacies, was the most common service followed by compounding in 74.7%, delivery 55%, charge accounts 43.9%, durable medical equipment 42.9%, blood pressure monitoring 35.8%, ostomy supplies 33.8%, diabetic teaching/monitoring 28.6%, speaking to groups about compliance 26.8%, providing compliance packaging 21.3%, 24-hour service 20.6%, refill reminders 15%, surgical appliance fittings 14.3%, free health screenings 12.8%, supply Jobst 10.3%, certified orthotist on staff 8.3%, mastectomy prosthesis 6.3%, registered nurse or physician assistant on staff 4.5%, and provide custom shoes 2.3% of respondents (Table I). In addition, the pharmacies were asked if they would be a designated caregiver pharmacy 75% responded positively.

Big "B," Drug Emporium, Fantle's, F & M Distributors, Giant, K-Mart, Peoples, Revco, Rite Aid, Safeway, Thrift, and Weis were included in chain stores. Of the total number of chain pharmacies in Maryland 32% responded to the survey. Of the chain stores that responded 88.4% provide a senior discount, 81.5% provide blood pressure monitoring, 32.2% provide charge accounts, 26% speak to groups about compliance, 19.2% provide delivery service, 17.8% provide diabetic teaching/monitoring, 12.3% provide durable medical equipment, 11.6% provide refill reminders, 6.8% provide ostomy supplies, 4.8% provide compliance packaging, 1.4% provide 24-hour service and surgical appliance fitting, and 0.7% provide a registered nurse or physician's assistant on staff (Table II). None of the chain stores that responded to the survey pro-

TABLE 1
Services Provided by Pharmacies in Maryland

Service	Percent of Respondents
Senior Discount	77.7%
Compounding	74.7%
Delivery	55.5%
Charge Accounts	43.9%
Durable Medical Equipment	42.9%
Blood Pressure Monitoring	35.8%
Ostomy Supplies	33.8%
Diabetic Teaching	28.6%
Speaking to groups about Compliance	26.8%
Compliance Packaging	21.3%
24-Hour Service	20.6%
Refill Reminders	15.0%
Surgical Appliance Fittings	14.3%
Free Health Screenings	12.8%
Jobst	10.3%
Certified Orthotist	8.3%
Mastectomy Prosthesis	6.3%
RN/PA on staff	4.5%
Custom Shoes	2.3%

vided mastectomy prosthesis, jobst, custom shoes, or had a certified orthotist on staff.

Fifty-five percent of the independent pharmacies in Maryland responded to the survey. Of those responding delivery was the most common service provided by 74.4% of pharmacies, followed by, compounding by 69.4%, durable medical equipment 59.3%, senior discount 50%, charge accounts 49.6%, ostomy supplies 48.4%, diabetic monitoring/teaching 37.2%, blood pressure monitoring/teaching 36.4%, 24-Hour service 31.0%, compliance packaging 30.2%, speaking to groups about compliance 26.7%, surgical appliance fittings 21.3%, refill reminders 16.7%, jobst 15.9%, certified orthotist on staff 12.8%, free health screenings 12.0%, mastectomy prosthesis 9.7%, RN/PA on staff 6.6%, and custom shoes 3.5% of respondents.

A comparison of services offered between chain and independent pharmacies can be found in Table IV. It is interesting to note that of those who responded, independent pharmacies provided a larger percentage of each service reported in this survey.

TABLE 2
Services Provided by
***Chain Pharmacies Responding**

Service	Percent
Senior Discount	88.4%
Compounding	81.5%
Blood Pressure Monitoring	39.0%
Charge Accounts	32.2%
Speak to Groups about Compliance	26.0%
Delivery	19.2%
Diabetic Teaching/Monitoring	17.8%
Durable Medical Equipment	12.3%
Refill Reminders	11.6%
Ostomy Supplies	6.8%
Compliance Packaging	4.8%
24-Hour Service	1.4%
Surgical Appliance Fitting	1.4%
RN/PA on staff	0.7%

* Big "B," Drug Emporium, Fantle's, F & M Distributors, Giant, K-Mart, Peoples, Revco, Rite Aid, Safeway, and Weis.

Discussion

The most confusion centered on compliance packaging. Included in compliance packaging are blister packs, bingo cards, calendar cards, bubble packs, and any other packaging which will assist the patient in taking their medication appropriately. Safety closures/non-safety closures are not considered compliance packaging. Non-safety closures do assist many elderly in retrieving their medication from the container. Also, packaging provided by the manufacturer, such as birth control pills, is compliance packaging but it is not an additional service provided by the pharmacy.

TABLE 3
Services Provided by
Independents Responding

Service	Percent
Delivery	74.4%
Compounding	69.4%
Durable Medical Equipment	59.3%
Senior Discount	50.0%
Charge Accounts	49.6%
Ostomy Supplies	48.4%
Diabetic Teaching/Monitoring	37.2%
Blood Pressure Monitoring/Teaching	36.4%
24-Hour Service	31.0%
Compliance Packaging	30.2%
Speaking to Groups about Compliance	26.7%
Surgical Appliance Fittings	21.3%
Refill Reminders	16.7%
Jobst	15.9%
Certified Orthotist	12.8%
Free Health Screenings	12.0%
Mastectomy Prothesis	9.7%
RN/PA on Staff	6.6%
Custom Shoes	3.5%

In order to simplify the survey a check list was used. This certainly can lead to different interpretations of the precise meaning of the services listed. For example, compounding may include adding water to an antibiotic or mixing two commercially available creams together. One may also interpret compounding to mean making suppositories, capsules, dermatology products not available commercially, or special pediatric preparations for children with serious illnesses. Other areas where interpretation may skew the results include ostomy supplies, durable medical equipment, blood pressure monitoring/teaching, and diabetic monitoring/teaching. Each of these services may be offered at different levels. The study did not allow for the stratification of services. Also, there has not yet been verification that the services stated are practiced on a regular basis.

The economic impact of providing services was not addressed. Many services may not be offered due to an adverse effect on the pharmacy's economic health. On the other hand some services may be more readily available for the pharmacy's economic benefit. Differentiation among those services would provide valuable information to our future entrepreneurs.

Continuous update of the database will be a difficult task. However, the most current accurate data is necessary so that patients may receive this valuable information.

The Maryland Office on Aging is interested in developing a list of pharmacies to which they could refer senior citizens for specific services. The relationship with the State Office on Aging could be mutually beneficial.

TABLE 4
Comparison of Services Provided by Chain versus Independent Pharmacies

*Service Number	Total Number	Number provided by Chains	Percent Independent	Percent Chains
1	220	28	87.3	12.7
2	85	2	91.8	8.2
3	151	57	62.3	37.7
4	122	26	78.7	21.3
5	135	10	92.6	7.4
6	171	18	89.5	10.5
7	60	17	71.7	28.3
8	82	2	97.6	2.4
9	25	0	100.0	0.0
10	175	47	73.1	26.9
11	9	0	100.0	0.0
12	18	1	94.5	5.5
13	51	20	60.8	39.2
14	107	38	64.5	35.5
15	298	119	60.1	39.9
16	57	2	96.5	3.5
17	41	0	100.0	0.0
18	33	0	100.0	0.0
19	310	129	58.4	41.6

* 1 = Delivery, 2 = Compliance Packaging, 3 = Blood Pressure Monitoring, 4 = Diabetic Teaching, 5 = Ostomy Supplies, 6 = Durable Medical Equipment, 7 = Refill Reminders, 8 = 24-hour Service, 9 = Mastectomy Prosthesis, 10 = Charge Accounts, 11 = Custom Shoes, 12 = RN/PA on staff, 13 = Free Health Screenings, 14 = Speaking to groups about compliance, 15 = Compounding, 16 = Surgical Appliance Fittings, 17 = Jobst, 18 = Certified Orthotist, 19 = Senior Discount.

Conclusions

Services which were excluded from the survey but would provide valuable information include: computerization, patient profiles, and patient counseling.

The preliminary study indicates there are a wide array of services provided by pharmacies across the state. Further study is needed to: 1. validate that stated services are provided, 2. stratify the level of service provided, 3. determine the economic impact of provided multiple services, and 4. update the database on a regular basis.

The information supplied by pharmacies throughout the state is being distributed to the general public at Caregiver Conferences. The Caregivers are grateful for the information you have provided.

Kathleen Gondek, M.S., is Project Director, Maryland Caregiver Program, Center For The Study of Pharmacy and Therapeutics For The Elderly, University of Maryland School of Pharmacy, 20 North Pine St., Baltimore, Maryland 21201.

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Dickinson's Pharmacy

by Jim Dickinson

The truth about generics. The current scandal about FDA approval of generic drugs has everybody asking: "Are generics safe?"

By the middle of August, this year-long federal investigation had caused thousands of anxious people to begin calling FDA in Washington, its regional offices around the country, and Capitol Hill—to say nothing of their own doctors and pharmacists.

The issue is both complicated and not as bad as you might think.

To understand it, you need to recognize that generic drug companies have a far different "culture," or mindset, than the big innovator drug firms. Until recently generic drug operators have mainly used their own money, rather than stock-market investors' funds.

That has let them take more chances in the marketplace than the big companies are known for taking.

The other thing you need to remember is that FDA doesn't do its own testing. It relies on the honesty of the drug companies that submit test data to FDA reviewers for assessment.

Although the risk-taking generic industry has had its ups and downs before, FDA has always managed to stay on top of it. That suddenly changed around 1985, hindsight now tells us.

That's when the 1984 Waxman-Hatch Drug Price Competition and Patent Term Restoration Act finally began allowing new generic copies of big post-1962 innovator drugs to enter the market.

It's also when a little-known FDA budget cut took place: the closure of the FDA Drug Chemistry Laboratories that used to analyze random samples of new products.

Nobody can say for sure how all this inter-relates, but my feeling is that some of the risk-takers decided it was getting safer to switch ingredients, fake test results, and bribe susceptible FDA employees to expedite the review of your drug while slowing down your competitor's.

The switching of ingredients had been an occasional characteristic of generic drug companies for years, and was something that the sampling program would catch from time to time.

There weren't a lot of switches, and they never involved active ingredients—just colors, binders, fillers, and so on. But they did occasionally affect dissolution (i.e., bioavailability).

The risk-takers thought it didn't matter if, when they ran out of one excipient during a run, they just (illegally) put in another. Whenever FDA caught up with these changes through its sampling program, the company would get a regulatory letter, and repeated offenses would result in a freeze of their new product approvals.

After the Drug Chemistry Laboratories closed and the sampling stopped, I believe the risk-takers' switching practices got more and more ambitious over time.

Now, I'm only talking about a minority of generic drug companies here. But since new companies began forming after 1984's new law came into being, it's hard to tell which firms were doing what without FDA's knowledge.

The Reagan Administration's official policy at FDA in those days were "voluntary compliance"—a naive idea that companies would do the right thing if only you were patient and gentle in educating them.

Then, sometime in 1987 or 1988, some risk-takers' switching became heavy-duty. Vitarine employees actually tipped Dyazide into their own triamterene/hydrochlorothiazide capsules and took them to be tested for bioequivalence. Naturally, the results were perfect, and FDA gave approval for marketing.

Several other companies were alleged to have done the same thing, and counting all the excipient-switching and data falsification FDA suddenly began discovering, dozens of generics have been recalled.

Are generics safe? When you consider that the only *documented* cases of active ingredient switching are about generic Dyazide copies, and when you consider that Dyazide is probably the toughest drug in the world to copy, then the answer is probably yes. (Dyazide's bioavailability is so poor and variable that better-bioavailability Maxzide was actually developed out of unsuccessful efforts to copy the SmithKline drug).

The excipient-switching is a serious problem, and FDA is reactivating its sampling program to deal with it. But the fact remains that we have no evidence of harm from the other risks that the generic risk-takers have been taking.

Incidentally, how sure are we that no brand-name companies ever get into this kind of hanky-panky with their generic lines? I'm told their corporate bureaucracies are too thick, with too many sign-offs and check-lists, to let them do what the lean-and-hungry, racy little generic guys can do.

Redundancy is something that the generic risk-takers said they couldn't afford!

This feature is presented on a grant from "Dickinson's Pharmacy—The Independent Voice," an 8-page practical monthly newsletter available from Ferdic, Inc., P.O. Box 848, Morgantown, WV 26507-0848 at an annual subscription fee of $45.

Exploring Alliance Between Pharmacists and Physicians

A new, independent nationwide survey reports that many doctors think of pharmacists as pill-dispensers, a view not shared by pharmacists, who see themselves as health care advisors.

Citing these divergent views as an example of the misunderstandings in their professional relationship, some two-thirds of the physicians interviewed listed filling prescriptions as the pharmacist's most important function, whereas more than half of the pharmacists interviewed said advising patients on general health matters was their most important function.

Clearly, doctors have a rather narrow and somewhat limited image of the pharmacist's role in the health care triangle of pharmacist, physician and patient.

Underscoring the vital importance of these professions to the nation's health care system, Schering Report XI, "Pharmacists and Physicians: Professional Allies or Professional Adversaries?," probes the various elements of the relationship, including both sides of the highly charged issues of generic substitution and physician dispensing of medication for a fee. The report also explores some of the reasons for the misunderstandings between pharmacists and doctors, and suggests steps to strengthen their "working bond" to enhance the quality of care that patients receive.

In the 1989 study, nearly 500 pharmacists and physicians across the country were interviewed in depth. Among the basic questions were: What does each side expect from the other and where do they feel they are being let down? How do personal attitudes and personalities affect the relationship? In what way does each side think they are misunderstood, underutilized or underappreciated? Finally, how can the relationship be improved?

Disparities between pharmacists' and physicians' views were highlighted on some specific activities that pharmacists regularly perform. For example, all pharmacists (100 percent) agreed that they should call the physician with any questions about a prescription. Close behind came consulting and advising patients on OTC medication (99 percent), cautioning patients about possible drug interactions (97 percent), providing verbal as well as written instructions on how to take medications (94 percent), explaining possible side effects (94 percent) and discussing patient profiles with the physician (89 percent).

Do doctors agree with the pharmacist's assessment? The study reported "perfect agreement, a bull's-eye 100 percent," on calling physicians with questions about a prescription, but fewer endorsements of other activities.

The greatest differences involved consulting on OTC products, with 75 percent of doctors voting "yes" compared to 99 percent for pharmacists; and discussing patient profiles with the physician, with pharmacists scoring 89 percent versus 69 percent for physicians.

On these issues, the report clearly underscores the fundamental differences between the two professions perceptions. Pharmacists see their task more in terms of patient service, counseling and advising, rather than just filling prescriptions. Physicians, on the other hand, see pharmacists as primarily filling prescriptions and providing patients with prescription information, not patient counseling.

Perhaps time itself will lend a hand in lessening the potential tensions in these specific areas. Analyzed by age, younger doctors showed a greater appreciation and understanding of pharmacists' activities than doctors with 10 years or more of experience. For example, 76 percent of older doctors endorsed pharmacists' OTC consultations versus 84 percent for younger doctors.

How do the two groups feel about each other and their professional relationship? On the whole, doctors are more satisfied than pharmacists, with 47 percent rating the relationship as excellent and 52 percent as good. Among pharmacists, 38 percent feel the relationship is excellent and 52 percent say it's good.

Among pharmacists and physicians who gave their relationship an excellent rating, the major reasons given were "work well together" and "willingness to communicate." In smaller towns, where pharmacists and physicians know each other by face as well as by first name, relations seem most cordial.

The Schering Report also probed the hidden likes and dislikes on both sides that affect the psyche of the relationship. Listing what they liked most about physicians, pharmacists (31 percent) said that "doctors respect pharmacists, treating us as professionals on par with other health care professionals." Twenty-eight percent cited "good communications," meaning doctors are easy to reach, easy to communicate with and easy to get along with. Next came "personal qualities" (17 percent), such as integrity, dedication and genuine concern for patients, followed by the doctor's "medical background and knowledge." Finally, 5 percent of pharmacists say there is "nothing to like" about doctors.

What do physicians like about

pharmacists? "Good communications"—the pharmacist's willingness to listen—headed the list (42 percent), with younger doctors listing this factor twice as often as their older counterparts. "Respect for doctors" and "the pharmacist's knowledge and caring about his patients" were also appreciated by physicians.

The fact that doctors are more likely than pharmacists to mention 'good communications' as what they like about the other side (42 percent versus 28 percent) suggests that pharmacists who want to make a good impression on physicians could profitably re-evaluate their communications skills and techniques.

On the negative side, the pharmacists' No. 1 dislike about physicians is that "doctors think they're better" (38 percent). The report noted that many pharmacists described this phenomenon in religious terms: "They get the feeling that they are God . . . They have a pedestal complex . . . Some of them play God . . . They have a feeling that they're God's people."

Next on the pharmacists' dislike list (29 percent) is poor communications, particularly for doctors who refuse to talk to pharmacists, leaving them hanging on the phone and often not calling them back for hours or even days.

Some pharmacists (9 percent) also disliked the personal qualities of doctors—their lack of dedication and poor treatment of patients. Translated: physicians do not give patients adequate information about their medical condition or medications, and do not spend enough time with them.

Finally, some pharmacists (5 percent) say they really dislike the doctor's terrible handwriting, adding that an apparently satisfied group of pharmacists (9 percent) feel there's nothing they find to dislike about doctors.

Physicians also had their say on what they dislike about pharmacists. Atop the list, however, was a bouquet not a bomb. Fully 30 percent of the doctors find absolutely nothing they dislike about pharmacists.

Citing specific dislikes, perceived pharmacist meddling in patient treatment rankled some doctors (27 percent). Said a South Carolina physician: "Pharmacists who diagnose patients' ailments are overstepping their professional limitations. I don't dispense medication, and pharmacists should not diagnose patients."

A tendency by some pharmacists to "push" generics (13 percent) is another source of annoyance. "Pharmacists substitute generics for brand-name drugs because they make more money from generics," according to an Arkansas doctor.

When doctors were asked if they found any differences between pharmacists in independent and chain pharmacies, about one-third reported "considerable differences." The doctors felt that independent pharmacists show more concern for patients, are more dedicated, work more closely with doctors and are easier to get along with.

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A publication
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The roots of some potential problems in the pharmacist-patient relationship came to light when both groups were asked to evaluate statements defining the pharmacist's image.

About 90 percent of community pharmacists felt strongly that they are:

- important partners in overall patient care;
- truly health care professionals;
- well educated in their profession; and
- sincerely concerned about the health of their patients.

There was also impressive agreement among community pharmacists that they provide high-quality service to patients (86 percent) and respect physicians' wishes regarding their patients (83 percent). About two-thirds felt they do provide valuable information to physicians.

The world of pharmacy was viewed differently by physicians. Only 54 percent of doctors strongly agreed that retail pharmacists are truly health care professionals—some 36 percentage points below the pharmacists' response—and only 52 percent felt that pharmacists are sincerely concerned about the health of their patients.

Another notably wide gap surfaced on the question of whether community pharmacists respect the physician's wishes for the patient, with 30 percent fewer doctors than pharmacists strongly agreeing.

Not all doctors are willing to respect pharmacists as fellow health care professionals. Worse, they are not all convinced that pharmacists are sincerely concerned about their patients' health.

Here again, the survey indicated, age and experience seem to influence the patient's judgment. Compared with their junior colleagues, more older doctors agree with the pharmacists' image of themselves as true health care professionals concerned with physicians' wishes for their patients.

The Schering Report also disclosed a gulf in perceptions in three

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other areas. Some doctors feel that pharmacists contact them for unimportant reasons (7 percent), that community pharmacists often provide medical advice they are not qualified to give (19 percent) and that community pharmacists sometimes overstep their professional responsibilities (12 percent).

How do physicians define overstepping professional responsibilities? "It means they object to the pharmacist trying to be pharmacist *and* physician, all at the same time, and they don't like the idea of pharmacists pushing generic drugs in defiance of physician specifications.

The study noted that, in the health care triangle, patients deal face-to-face with both pharmacists and physicians while the pharmacist-physician relationship is "faceless," being conducted primarily on the telephone. While undeniably vital in maintaining fast, convenient communications, the telephone, the Schering Report suggests, may also be undermining that relationship in subtle ways. Both sides may be increasingly afflicted by telephone burnout.

Pharmacists estimated that they make an average of 25 calls a day to physicians' offices. One call in five is a conversation with the doctor, while the other four are with a member of the doctor's staff.

For their part, doctors said their office staffs receive slightly over six calls a day from pharmacists, two of which they take personally. Six calls grossly underestimates the true volume of calls—very likely because the physician's staff does not always tell the doctor about calls that do not require his personal attention, at least by their definition.

What are those calls all about? The No. 1 reason (77 percent) is simply for authorization of refills, followed by the need to seek clarification about the dosage or a possible error in the original prescription (53 percent). Less frequent but still important reasons for possible drug interactions (22 percent), verification of a new prescription (18 percent) and a "simply can't read the doctor's handwriting" (16 percent).

Since the doctor's office staff handles most incoming calls from pharmacists, not surprisingly, physicians gave some different reasons for pharmacists' calls, the study reported. Agreeing with pharmacists, refill authorizations (68 percent) led the doctors' list of reasons. Only 29 percent mentioned calls for errors and clarifications, contrasted with 53 percent for pharmacists.

The Schering Report suggests that these differing results may be traced partly to the fact that a doctor's staff handles most of the calls. There might also be a reluctance on the doctor's part to admit that the prescriptions they write are ever less than perfect, or that another health care professional would dare find fault with one of their prescriptions.

What about calls coming the other way, from doctors to pharmacists? Pharmacists said they receive an average of 29 such calls a day, with roughly one in four from the physician personally. Physicians, however, said their offices make about eight calls a day to pharmacies, with an average of three personal calls. The study noted that the doctors' reported eight calls a day to pharmacists is probably an underestimate as their office staffs may work independently without reporting every phone call to the doctor.

Pharmacists said the calls from doctor's offices are, as expected, mostly calling in new prescriptions (91 percent), refill authorizations (36 percent), requests for information and clarification on prescriptions (25 percent) and questions about possible drug interactions (22 percent).

Doctors ranked the reasons in the same order, but only 55 percent mentioned calling in prescriptions, perhaps because that job is often assigned to an office staffer.

Exploring ways in which the telephone may be injecting tension into the pharmacist-physician relationship, the Schering Report observed that, for many pharmacists, calling a doctor's office can be as frustrating as one endless hold.

Pharmacists believe they are unfairly blocked from getting through to doctors even when there are sound reasons to talk directly with them. The reason most mentioned was possible prescription errors or for other clarification (41 percent). Other reasons: the staff is 'simply not qualified to answer' (27 percent) and possible drug interactions (26 percent), followed by patient compliance problems, verification of new prescriptions and questions about refills, and, once, again, the physician's handwriting.

What kind of phone calls do doctors prefer to handle personally? Twenty-nine percent said they take *all* calls from pharmacists, 25 percent are receptive to calls dealing with possible prescription errors and need for clarifications, and 15 percent mentioned calls on possible drug interactions.

It seems evident that doctors recognize the pharmacist's expertise in pharmacology, and that pharmacists are, indeed, a good source of information on medications.

The Schering Report went on to suggest ways to remove some of the static from the pharmacist-physician relationship on telephone matters. Pharmacists can help by making it clear to the doctor's staff the precise reason they need to talk to the doctor personally. Doctors, on their part, can help by communicating clearly to their staffs the reasons for putting calls through.

The study also revealed unauthorized substitution as another point of friction. For example, 9 percent of physicians feel that unauthorized substitution—involving either generics or another brand—occurs frequently, 18 percent feel it happens often and 26 percent believe it happens sometimes. The rest (47 percent) think that pharmacists comply with the doctor's specifications and never substitute without authorization.

About half of the doctors who feel that unauthorized substitution occurs feel it's a serious problem. They usually find out about a substitution from patients themselves, when the patients question a substitution or when they show the medication to the doctor.

The doctor's first line of action in this case is to talk to the pharmacist. A small number of physicians said they would take even stronger action, such as going to the state Board of Pharmacy or recommending that patients switch pharmacies.

Another sensitive point, according to the study, is physician dispensing of medication for a fee. Pharmacists who were willing to venture an "educated guess" said that about one in 10 doctors in their community was dispensing medication for payment. Why? Three-quarters of the pharmacists said the doctor's No. 1 reason is to make more money, and about 20 percent said it's primarily for the convenience of patients.

When asked whether they favored or opposed the practice, some 17 percent of physicians said they had not yet made up their mind either way. Among doctors who had an opinion, 60 percent opposed and 40 percent favored physician dispensing.

The Schering Report suggests a rising ride of sentiment among doctors in favor of the practice. Older doctors are opposed two to one, but the vote splits 50-50 among younger doctors, those practicing for 10 years or less.

The dispensing issue divides into two camps. Many doctors in favor cite convenience for the patient as well as saving money for the patient. Opposing doctors say it's simply not their job; they're already too busy anyway. Doctors should only be doctors.

Schering Report XI emphasized that the pharmacist-physician relationship is a vital element in the nation's health care system and flourishes in spite of several apparent differences in attitudes and perceptions.

There is more that unites the two professions than divides them. That tie is a dedication to providing the patient with the best possible health care.

TEST YOURSELF

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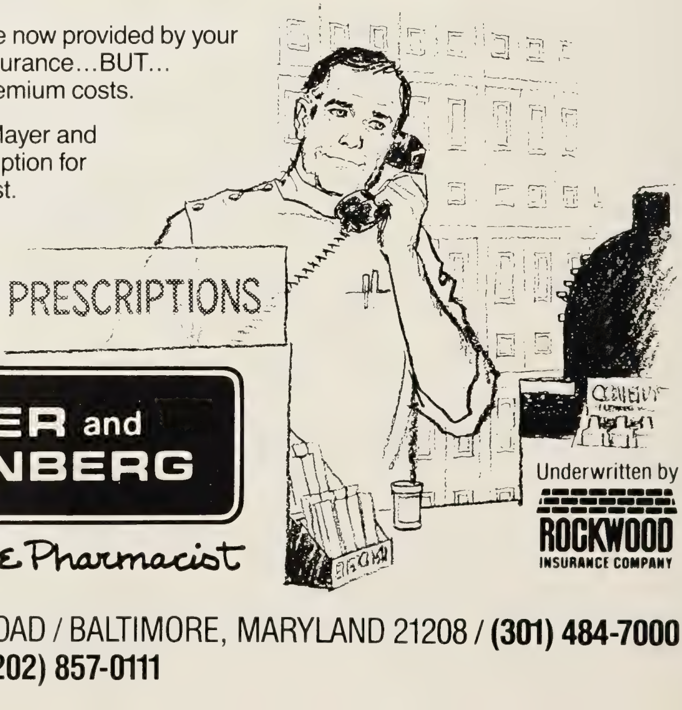

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The Pharmacist's Role in Emergency Care

Pharmacists are in a unique position to assist emergency physicians in setting priorities for patient treatment.

by George Podgorny, M.D.

Emergency care in the United States involves approximately 80 million emergency department visits per year. This number does not include visits to veteran's hospitals, military hospitals or hospitals in Puerto Rico. Ten million of the visits require immediate emergency care in cases in which life is in jeopardy or an important part of the body may be lost.

Hospital admissions through emergency departments are increasing at the rate of 10% a year. In some hospitals, as many as 60–70% of patients are admitted through the emergency department. Because patients are coming in sicker and later, the average length of stay is longer. When we then consider that a substantial percentage of malpractice claims originate in the emergency department, we're looking at considerable issues involving substantial costs and quality of care.

Pharmacists Have a Unique Role in Emergency Care

Pharmacists are especially trained to play a vital role in protecting the health of their patients. They double check on what the doctor has prescribed and dispense only the highest quality pharmaceuticals and over the counter medications. They are also available to patients for general health information and guidance about their medications. These services are unique. Counsel is free, easily accessible without an appointment, and pharmacists are usually easy to talk to.

A pharmacist's influence is widespread. There isn't a member of the public who has not consulted a pharmacist about a health problem. There are few patients who do not go to a pharmacist to fill their doctor's prescription.

Pharmacists can usually identify their patient's diagnosis, based on the prescription presented. Pharmacists are in a unique position to recognize "hidden" conditions that, if not known in a timely manner in an emergency setting, could jeopardize life.

Patients often have three or four doctors, but only one pharmacist. Pharmacists see more patients than the average physician. Pharmacists often have the best overall data; they fill prescriptions and can often identify the condition for which it is being prescribed. They know if there is a potential drug reaction with medications prescribed by another physician.

A relatively simple solution to communicate this vital information is to have an emergency medical identification system available to those who have hidden health problems or take medications regularly. These patients need a system to speak for them when they cannot do so for themselves.

A preliminary study conducted by the author and funded by The Robert Wood Johnson Foundation disclosed that in one urban/rural hospital emergency unit, in approximately 6% of the visits, medical care would have been expedited if the identifying and medical information had been available in a timely manner.

This experience can be expanded to show the need across the United States. Out of the approximately 220,000 people in this country who visit emergency departments each day, 13,200 cases daily, or 4,818,000 per year would benefit from emergency medical information. The best system is currently provided by Medic Alert Foundation International.

Pharmacists today are in a unique position to provide added services to their patients who need emergency medical identification. Although the time spent talking to a patient about emergency protection will be limited, its potential rewards are great and satisfying. Expediency and speed are very important in an emergency.

Medic Alert Provides Critical Information

The Medic Alert emblem provides emergency department staff with information so that they can set priorities in diagnosis and treatment. The cases outlined below describe why this information is so critical.

Epilepsy: The patient is a young man who is intoxicated and has a significant bump on the head. Under this stress and a delay in taking his regular medication, Dilantin, a seizure develops. Without additional information, the doctor may think the problem is brain injury.

Taking Coumadin: Because of the blood thinning characteristics of Coumadin, a person taking this compound who is involved in an accident may bleed particularly heavily. The attending physician may misdiagnose a bleeding disorder. If known, the bleeding could be easily controlled.

Adrenal Insufficiency: With this condition, the patient might stay in intensive care from 12–48 hours, just for a diagnostic workup. If the person has just experienced a trauma from an accident or has Addison's Disease, their blood pressure will drop, and the patient will be opened to check for severe bleeding. Since there is no bleeding, they may be treated for a heart attack, with no response. As a result, the search will go on.

If the condition is known, steroids will be provided and, in 10–15 minutes, recovery will begin. The patient may not even have to enter the hospital.

Hypertension: If a person's normal blood pressure is 180 over 120, but, with beta blockers, is 120 over 60, the physician may believe the patient is in a great degree of shock. Diagnosis is wrong from the beginning. Knowing that the patient is taking a beta blocker is critical.

Heart Valves: Today's synthetic heart valves are quiet. While metal and plastic valves can be seen on an X-ray, dried valves made from pig tissue cannot be seen. Rapid heartbeat resulting from bleeding presents a problem. The normal heart can reach 260 beats per minute and still be efficient, while mechanical and artificial valves will fail under these conditions.

Angina: It is assumed when blood pressure is low or a person has severe chest or arm pains that it is a heart attack, which must take first priority in treatment. If an unconscious or incoherent patient with angina enters the emergency department with a head injury and/or broken leg, the first priority becomes something other than the angina.

Hypoglycemia: If hypoglycemia is unchecked, it can result in brain damage. If the emergency physician is aware of existing hypoglycemia, paramedics will be instructed to give intravenous glucose. In this instance, appropriate treatment will obviate the need for the patient to be admitted to the hospital.

Taking heart medications such as digitalis: The heart rate is slower than usual and, during an EKG, a physician can expect certain abnormalities. However, without knowing the person is on digitalis, the doctor's diagnosis may be impending heart attack and be treated as such.

Coronary Bypass Graft: If the overall surgical experience is positive, after a month or two medication does not need to be continued. If the results are fair, medication will be continued, and this needs to be known. In either case, the bypass indicates the person has a serious coronary artery problem. A history of heart surgery is critical information for first responders. The patient's sternum has been split during surgery and may be broken again during CPR, or CPR itself may not be as effective due to changes from past surgery.

Diabetes: Most hospitals today have an Accuchek device that pricks the finger, takes a drop of blood, and, within 60 seconds, determines fairly accurate the blood sugar level. Regular lab reports take more than an hour. This is another case where the paramedic can, with approval, provide treatment if the condition is known. One of the big problems is that people with diabetes are often involved in situations where they behave as if they are drunk, can't speak for themselves and end up in the police drunk tank. Without treatment, brain damage can result.

Asthma: A young man of 25 falls down drunk and hits his head. Disoriented, he doesn't say he has asthma. He has only a few stitches in the head and is kept 24 hours for observation at the hospital. Without proper medication for asthma, complications begin.

A second concern is that a person with asthma and emphysema is usually over the age of 45. The patient may be addicted to steroids, and, if put to sleep, may die if the condition is not known. Certain medications should not be given to people with asthma. In treating a

Pre-existing Conditions Important to Emergency Personnel in the First Minutes of an Emergency

dition diagnosis

Abnormal EKG
Adrenal Insufficiency
Alcoholism
Alzheimer's/memory impairment
Angina
Asthma
Bleeding disorder
Blindness
Blood type
Cardiac Dysrhythmia
Cataracts
Cerebro Vascular Accident
Clotting Disorder
Coronary Bypass Graft
Deafness
Diabetes/Insulin dependent
Diabetes/non-Insulin dependent
Glaucoma
Heart Valve Prosthesis
Hemolytic Anemia
Hypertension
Hypoglycemia
Laryngectomy
Leukemia
Hyperthermia
Myasthenia Gravis
Pacemaker
Renal failure/Hemodialysis
Seizure Disorder
Sickle Cell Anemia
Situs Inversus

Allergies or sensitivities

Aspirin
Barbiturates
Codeine
Demerol
Horse Serum
Lidocaine
Morphine
All Mycins
Novocaine
Penicillin
Stings (bee, hornet, wasp)
Sulfa
Tetracycline
X-ray dyes, I.V.P.
Iodine dyes

Regular Medications

Antianginal
Antiarrhythmic
Anticonvulsant
Antihistamines (prolonged use)
Beta Blocker
Cortisone/steroids

Special Needs:

Contact Lenses
Organ Donor
Living Will

broken leg, the patient is put under for 10–15 minutes while the leg is reset. A mask is used to put the patient to sleep. The patient may develop asthma, and there is no tube to keep the airway open.

Alzheimers/memory impairment: There are 2.5 million middle-aged and elderly people with Alzheimers. These patients cannot accurately answer questions to assist in their diagnosis. Tragically, thousands of Alzheimers patients are lost every year, when they become disoriented and wander away.

Myasthenia Gravis: This is a problem of the nerves at the synapse. If the patient doesn't take the medication, he/she becomes too weak to breathe. The condition is very difficult to diagnose and is often diagnosed too late.

Protecting Your Patients with an Effective Medical Information System

It is important for pharmacists to know what really works in the emergency setting. There are many cards and trinkets that do not provide adequate protection. Very few cards reach the emergency department. In many states it is illegal to do a wallet or purse search. In states where it is legal, the search is not performed because of liability problems. In the event of an accident, police officers often retain the wallet for investigative reports.

Pre-engraved bracelets are extremely limited. They are not "updatable"; they are limited to a single condition; and they do not provide a telephone "hot line" to secure additional patient information. Listing a single condition is often not helpful. "Heart Condition" is just not specific enough.

The most complete and advanced medical information system in the United States today is Medic Alert Foundation International, which is also a national health organization.

The Medic Alert system works in four ways:

- Medic Alert offers personalized emblems with the most critical medical data engraved.
- Medic Alert's 24-hour toll-free hot line (accessible anywhere in the world) immediately identifies the patient and provides additional critical information. When consultation is needed, a physician's or specialist's telephone number is available. The persons to notify in the event of an emergency are listed. The name and number of the person's pharmacy is provided, so that the pharmacist can be called for additional consultation on new drugs, special patient information, etc.
- Medic Alert has an annually-issued wallet card which includes all critical patient information.
- As a patient's medical information changes, Medic Alert's confidential records are updated and recorded on a sophisticated, computerized medical records system.

Medic Alert is endorsed by APhA, NARD, ASHP, 26 state pharmacy associations and almost every national medical and health association in the United States, including the American College of Emergency Physicians and the American Hospital Association.

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Washington, DC 20210

Medic Alert has developed 33 years of credibility, has more than 2.8 million members (1.8 in the United States) and serves 34 countries through 21 affiliates throughout the world.

A National Pharmacy Task Force provides ongoing leadership to Medic Alert's pharmacy program, and ICI Pharmaceuticals Group provides a $100,000 public service grant each year to assist in expanding this national program. Today more than 14,000 pharmacies are committed to protecting their patients with Medic Alert, and approximately 500 pharmacists' patients register each week for Medic Alert protection.

Pharmacists Can Assist Emergency Physicians

Pharmacists can assist emergency physicians in setting priorities for emergency treatment for their patients.

Make a serious effort to register every patient in need of Medic Alert protection. Through the few examples in this article, it is apparent that the information is critical in saving time, reducing trauma, cutting needless costs and, most importantly, saving lives.

Editor's Note: To participate in nonprofit Medic Alert Foundation, call Field Services Division, (800) ID ALERT, or write Medic Alert, Turlock, Calif. 95381.

George Podgorny, M.D., is past president of the American College of Emergency Physicians and associate professor, Clinical Surgery, at Bowman Gray School of Medicine, Wake Forest University.

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BLOOD PRESSURE GLOSSARY OF TERMS

Aldosterone—A steroid hormone whose major action is to facilitate potassium exchange for sodium in the kidney.

Angiotensin I—An inactive decapeptide produced by enzymatic action of renin upon a serum alpha$_2$ globulin (angiotensinogen) formed by the liver.

Angiotensin II—An octapeptide formed by the enzymatic action of angiotensin converting enzyme on angiotensin I. Angiotensin II causes vasoconstriction and stimulation of aldosterone secretion from the adrenal gland.

Angiotensinogen—A tetradecapeptide that is converted by the enzyme renin to angiotensin I.

Beta Blocker—An agent that inhibits catecholamine (which regulates the tone, resistance, and caliber of blood vessels) binding at beta receptor sites throughout the body and it is therefore effective in patients with arrhythmias, hypertension, or angina pectoris.

Bradycardia—Slowness of the heartbeat, usually defined as a rate under 60 beats per minute.

Bradykinin—A polypeptide formed in the blood that stimulates visceral smooth muscle but relaxes vascular smooth muscle, and thus produces vasodilation.

Calcium Channel Blocker—An agent that depresses cardiac contraction and dilates peripheral arterioles by preventing the flow of calcium ions through the slow calcium channels.

Diuretic—An agent that promotes the excretion of urine.

Dysgeusia—Impairment of the taste sense.

Esterification—The process of converting an acid to an ester (a compound formed from an alcohol and an acid by the removal of water).

Globulin—Name for a family of plasma proteins.

Glomerulonephritis—Renal disease characterized by wide-spread inflammatory changes in glomeruli of the kidney.

Hepatic—Relating to the liver.

Inotropic—Referring to the strength of muscular contraction.

Myocardial hypertrophy—An increase in mass of the heart muscle.

Natriuretic—Pertaining to the excretion of abnormal amounts of sodium in the urine.

Neutropenia—An abnormally low number of neutrophilic white blood cells in the circulating blood.

Peptide—A compound of two or more amino acids in which the carboxyl group of one is united with the amino group of the other.

Prodrug—A compound that, on administration, must undergo chemical conversion by metabolic processes before becoming an active pharmacological agent.

Proteinuria—The excretion of a greater than normal amount of protein in the urine—usually defined as greater than 200 mg per 24 hours.

Renin—A proteolytic enzyme synthesized, stored and secreted primarily by the juxtaglomerular cells of the kidney; plays a role in regulation of blood pressure by catalyzing the conversion of angiotensinogen to angiotensin I.

Renovascular—Pertaining to the blood vessels of the kidney.

Stenosis—A narrowing of any canal.

Sulfhydryl group—A univalent sulfur-hydrogen radical, usually attached to a carbon chain or a benzene ring. Sulfhydryl groups are necessary for many enzyme reactions.

Tachycardia—Rapid beating of the heart, usually defined as a rate over 100 beats per minute.

Thiazide Diuretic—A chemical class of diuretics that act by inhibiting the reabsorption of sodium in the proximal renal tubule and stimulating chloride excretion, with resultant increase in excretion of water.

Vasoconstrictor—An agent that causes narrowing of the blood vessels.

Vasodilator—An agent that causes dilation of the blood vessels.

Vasospasm—Transitory contraction of the muscular walls of the blood vessels.

MEMBER LETTERS

Pharmacist Jane in Baltimore
c/o the Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

Dear Pharmacist Jane:

I heard your call-in to the Sonya Friedman show yesterday which dealt with the current head-line making generic drug issues. You expressed concern over the number of drug recalls these days and said part of the problem was that the reason for the recall is not always given.

Manufacturers are requested to notify the Food and Drug Administration when they recall a batch of a drug and state why they are recalling it. FDA puts out a notice each week providing those facts. The newsletters and journals you read may carry all or part of these notices, at their discretion.

Since the first of 1989, *USP DI Updates* have carried a continuously updated cumulative 6-month list of recalls. The format is organized so that the reason for each recall shows up in a specific tabular column and is easy to see. Besides being helpful in case you miss the weekly recall announcements, the 6-month cumulative list—being cross-indexed—is useful in revealing which drug products and which manufacturers are currently having the most difficulty.

Sincerely,
William M. Heller, P.D.
Executive Director
United Pharmacopeial Convention, Inc.

PHARMACIST'S EXPAND PROGRAM TO AID EMERGENCY VICTIMS

—Of the more than 200,000 Americans who make unscheduled trips to hospital emergency rooms every day, one in four may have a hidden medical condition such as diabetes, heart disease, asthma, or serious allergies to certain medications like antibiotics or pain killers. In an emergency, these patients may be unconscious or incoherent and may be particularly vulnerable to inadequate or inappropriate treatment —or treatment that might simply be started too late.

This can be avoided if emergency personnel have immediate access to key facts about the patient's condition or medication—information that's available in seconds if the patient is wearing a Medic Alert® bracelet or neck chain.

Nonprofit Medic Alert is the only internationally recognized emergency medical system that maintains a data base to provide vital health information to emergency personnel around the world, 24-hours a day via Medic Alert's medical records hot line, seven days a week. It's the only system endorsed by emergency room physicians, ambulance personnel, the nation's hospitals—and now, by national and state pharmacy associations.

A Medic Alert Pharmacy Task Group, comprised of representatives from such key national pharmacy organizations as APhA, NARD, ASHP, NACDS, NCSAEC, and NWDA, has been created to encourage an increased role for pharmacists in protecting the lives of their patients who may be at special risk in emergencies. Since the program began only three years ago, more than 14,000 pharmacies have begun promoting the nonprofit Medic Alert system. As a result, some 100,000 pharmacy patients have been enrolled in the lifesaving Medic Alert program, more than 20,000 patients have depended on the service in an emergency—and more than 3,000 lives were saved! All the result of direct pharmacist involvement.

The Pharmacy Task Group's goal for 1989 is to double the number of pharmacies promoting the Medic Alert emergency system. According to Joel Tau, Chairman of the Medic Alert Pharmacy Task Group which designed and implemented the program, "we're encouraged by the fact that each month, nearly 3000 pharmacies are being added to the Medic Alert network. However, the potential for increasing the number of pharmacists involved in this project has hardly been tapped. Our goal is to increase the number of participating independent and chain pharmacies from just over 14,000 to at least 25,000 by the end of 1989," Tau added.

To support this effort, the Pharmacy Task Group will kick off a major national public education campaign in August aimed at bringing the important Medic Alert message directly to consumers—and urging them to task their pharmacist for information and enrollment applications. Cooperating national pharmacy associations will be actively promoting the program among their members, and each of the nation's 50 state pharmacy associations will be supporting this effort with television and radio public service announcements and through articles in local newspapers and professional journals.

In addition, the Medic Alert Foundation will contact nonparticipating pharmacies so that those interested will receive a starter kit containing patient information, patient enrollment forms, and point-of-sale display materials. The substantial costs involved in the production of patient education materials and public service announcements have been underwritten through an educational grant from ICI Pharmaceuticals Group.

Nonprofit Medic Alert is the only internationally recognized compehensive emergency medical information system that provides emergency personnel with vital patient information quickly and accurately 24-hours-a-day, 7-days-a-week. More than 1.8 million Americans are already enrolled in Medic Alert, and over a million more are enrolled through Medic Alert affiliates in 22 countries abroad.

To receive pharmacy starter kits, or more information about the program, call Rich Haggard, % the National Medical Alert Pharmacy Programs Professional Support Center 1-800-736-3342.

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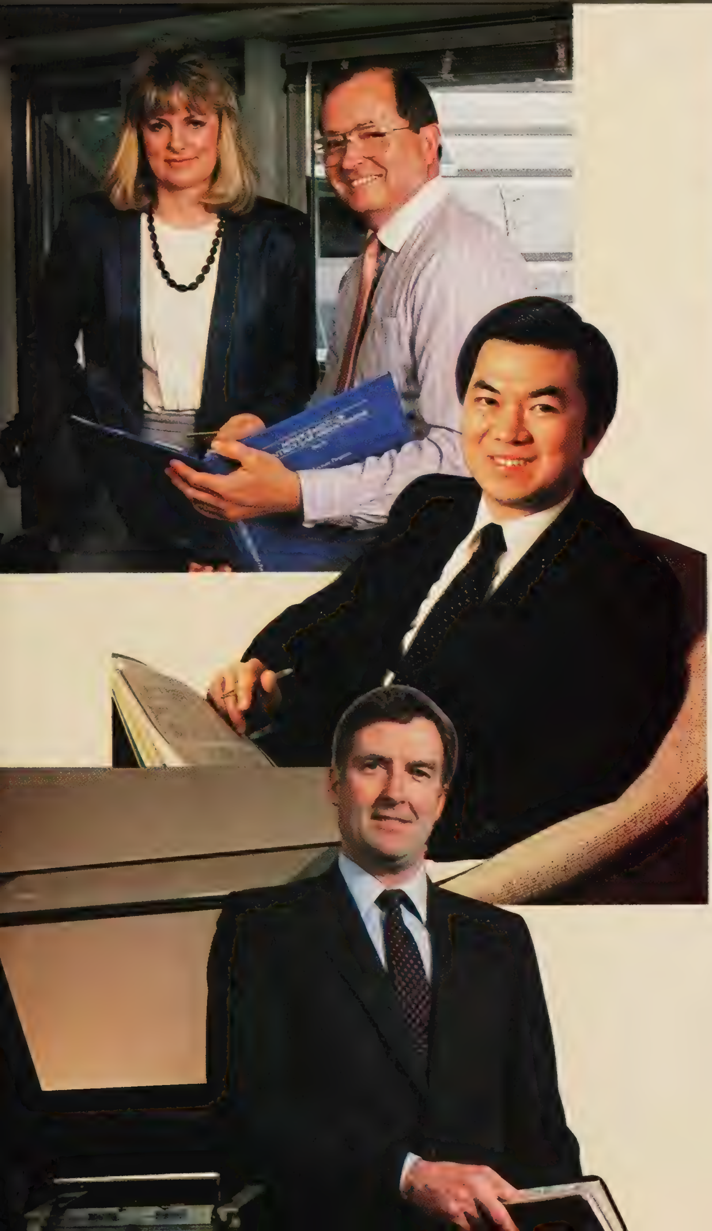

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People like Thomas Chin, PharmD, Manager, Medical Information Services (center), Laura McGuire, RN, Assistant Director, Clinical Investigation (above, right), and Kathryn Riccio, Manager, Medical Education and John Elliott, RPh, Manager, Conventions and Scientific Exhibits (above, left).

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Ramada Inn, Annapolis

PROGRAM

8:00 am	Continental Breakfast Registration
8:45 am	Presidential Welcome Nathaniel Futeral, P.D.
9:00 am	Continuing Education Seminar *New Drug Update for 1990* presented by: Richard Wuest, Pharm.D. Thomas A. Gossel, Ph.D.
12:30 pm	Luncheon MPhA House of Delegates Meeting Murhl Flowers, P.D. Speaker of the House presiding
2:00 pm	*New Drug Update for 1990* continued
4:00 pm	Wine & Cheese Reception

REGISTRATION

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MAIN DECK — outside stateroom, two lower beds.	D	~~1785~~	1508
"A" DECK — outside stateroom, two lower beds.	E	~~1710~~	1445
"B" DECK — outside stateroom, two lower beds.	F	~~1650~~	1395
PROMENADE DECK — inside stateroom, two lower beds. TWEEN DECK — inside stateroom, two lower beds. SHOWTIME DECK — inside stateroom, two lower beds.	G	~~1645~~	1390
MAIN DECK — inside stateroom, two lower beds.	H	~~1620~~	1369

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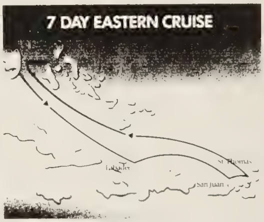

DAY	PORT	ARRIVE	DEPART
Sat	Miami, Florida		5:30 PM
Sun	At Sea	Cruising to Labadee	
Mon	Labadee, Haiti	8:00 AM	4:00 PM
Tues	San Juan, Puerto Rico	12:00 Noon	2:00 AM (Wed)
Wed	St. Thomas, U.S.V.I.	8:00 AM	6:00 PM
Thur	At Sea	Cruising off coast of Hispaniola	
Fri	At Sea	Cruising to Florida	
Sat	Miami, Florida	8:30 AM	

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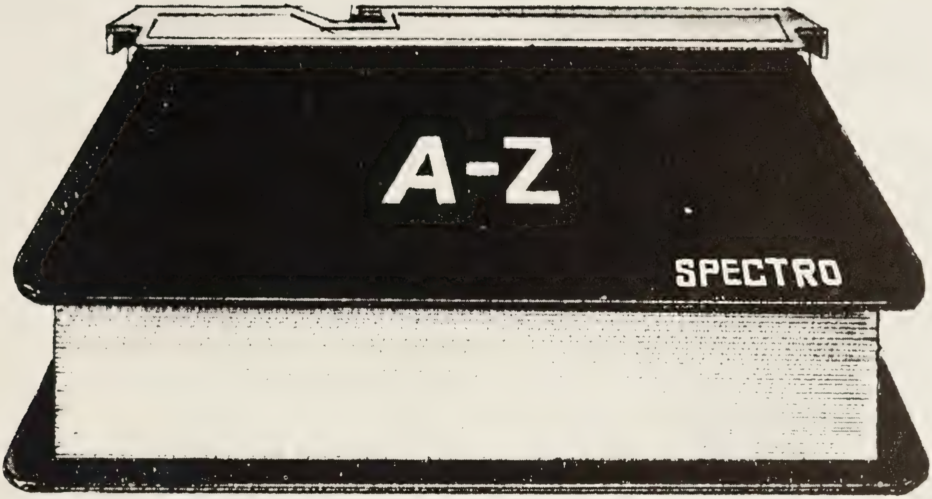

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SPECTRO INDUSTRIES

USP
DRUG PRODUCT QUALITY
Review
A PUBLICATION OF THE USP DRUG PRODUCT
PROBLEM REPORTING PROGRAM

No. 8

FOOD SUPPLEMENT PROBLEMS

Inadequate dissolution of various dietary supplements has been the subject of several DPPR reports over the past year. These reports involved a multiple vitamin supplement and various calcium products with both in-vivo and in-vitro dissolution problems.

The DPPR reports received on calcium products were sparked by the results of a published study by the University of Maryland College of Pharmacy which concluded that a number of Calcium Carbonate products failed USP dissolution specifications (Note: USP XXII requires that not less than 75% be dissolved in 30 minutes). Five consumers and pharmacists who "tested" their calcium products reported to DPPR that they observed no significant dissolution after an hour or longer. One DPPR report mentioned undissolved calcium tablets that were almost mistaken for bladder stones on the patient's x-ray.

Calcium tablets were not the only products reported with dissolution problems. Two additional DPPR reports were received regarding a single multiple vitamin product that failed to dissolve in-vivo. In one case, an abdominal x-ray revealed undissolved tablets in the patient's gastrointestinal tract. Subsequent x-rays determined that the tablets remained in the right lower quadrant undissolved after six weeks. In the second case, the tablets were excreted whole in the same form as ingested.

• • •

USP Review

Unless the product makes a therapeutic claim, a vitamin product is usually regulated by the Food and Drug Administration as a food (ie. a nutritional supplement or a dietary supplement) rather than as a drug. Many pharmacists and health professionals take for granted that since these products are dosage forms, they conform to Pharmacopeial standards whether or not they bear the initials "USP" on the label. While this is true for drugs, it may not necessarily be true for food supplements.

Presently, only those food supplements that state "USP" on the label can be held directly accountable to USP standards under the Federal Food, Drug and Cosmetic Act. FDA has indicated it now considers dietary calcium supplements, which fail the USP disintegration and dissolution standards, to be in violation of the misbranding (Sec. 403(a)(1) and Sec. 403(j)) and adulteration (Sec. 402(a)(3) unfit for food) provisions of the Federal Food, Drug and Cosmetic Act. In order to help ensure that the vitamin products they sell are of suitable quality, pharmacists should ask for a statement in writing from the manufacturer verifying either that the product does purport to meet USP standards or to determine what standards of quality the product does purport to meet. Such a representation by a vendor might at least be helpful under contract or commercial law principles in the event a problem should arise.

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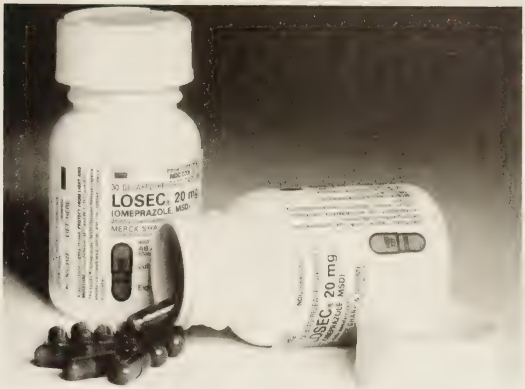
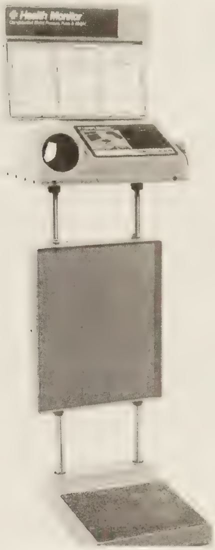
Issued 8/89

Bausch & Lomb has introduced Sensitive Eyes Sterile Saline Spray, a new preservative-free, borate buffered formula aerosol for soft contact lens wearers. The new saline spray will be available in a 12 fluid ounce size.

Glenbrook Laboratories has announced the introduction of Therapy BAYER aspirin, an enteric-coated aspirin packaged in caplet counts of 50 and 100. The enteric coating will allow the caplet to pass through the stomach to the intestine before dissolving, providing protection against stomach upset.



Merck has introduced Losec (omeprazole), a new once-daily oral medication for short-term treatment of symtomatic gastroesophageal reflux disease. Losec is the first of a new class of drugs called acid pump inhibitors to be approved by the FDA.



CardioAnalysis Systems has recently begun providing its automatic blood pressure measuring equipment to pharmacies. These measure blood pressure from the forearm using the oscillometric method. For more information call 1-800-543-2787.

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Continuing Education Quiz

The Maryland Pharmacist **NOVEMBER, 1989**

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by March 1, 1990. A continuing education certificate for one contact credit) will be mailed to you within 30 days. Please type or print clearly.

Name ______________________________

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Is this program used to meet your mandatory CE? [ ] Yes [ ] No

Did this article achieve its stated objectives? [ ] Yes [ ] No

How long did it take you to complete the program? __________ minutes

OTC Contraceptive Products

1. The herpes organism that causes genital infections is H:
   a. gonorrhea.
   b. simplex.
   c. varicella.
   d. zoster.

2. Which of the following types of OTC vaginal contraceptives is considered to be more effective than the other three listed?
   a. Aerosols
   b. Creams
   c. Gels
   d. Suppositories

3. The spermicide that is contained in the OTC contraceptive sponge is:
   a. menfegol.
   b. nonoxynol.
   c. octoxynol.

4. Animal skin condoms are obtained from the intestine of:
   a. cows.
   b. hogs.
   c. horses.
   d. lambs.

5. The principle ingredients used in most OTC spermicidal products are:
   a. antimicrobials.
   b. defrothicants.
   c. lubricants.
   d. surfactants.

6. Individuals using which of the following types of OTC contraceptive products should be made aware that there is a lag time between application and effective release of the active ingredients?
   a. Cream
   b. Foam
   c. Jelly
   d. Suppository

7. The OTC contraceptive method that theoretically should be 100% effective is/are the:
   a. aerosol foam
   b. gels and creams
   c. contraceptive sponge
   d. condom

8. Part of the action of the OTC spermicides is that they decrease the ability of sperm to metabolize which of the following sugars?
   a. Dextrose
   b. Galactose
   c. Fructose
   d. Ribose

9. The organism that causes toxic shock syndrome is:
   a. *Haemophilus vaginalis.*
   b. *Pseudomonas aeruginosa.*
   c. *Staphylococcus aureus.*
   d. *Streptococcus hemolytica.*

10. The active ingredient in the greatest number of OTC spermicide products is:
    a. menfegol.
    b. nonoxynol.
    c. octoxynol.

Classified

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THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Santi V. Lusco at 254-1772.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

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The Maryland Pharmacist

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Happy Holidays!

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A State of the Association Report: Looking Forward

Great things have happened to MPhA this year, and even better times are ahead! Your association has promised to *listen* to you and provide the services and activities *you* want, when you want them.

During the first half of my term as MPhA President, we have accomplished much. Membership increased by more than 200 pharmacists. A complete revision of the monthly newsletter now brings more news to you in an easy-to-read format. Information on upcoming events, meetings, and continuing education opportunities are now distributed to all members well in advance so that *everyone* can make plans to attend. MPhA has been a national leader in helping pharmacists combat unfair and discriminatory reimbursements by third-parties. Our DUR program has been recognized as a model for similar programs in other states. And, of course, MPhA's 1989 legislative accomplishments are well known to all members thanks to the exceptional work of our lobbyist, Robin Shaivitz.

As we look forward to 1990, MPhA has several major events planned of which members must take advantage. Our third annual Legislative Breakfast in Annapolis has been scheduled for February 9, 1990 at the Radisson Hotel. Invitations will be mailed to all state delegates and senators in January. I encourage each of you to call your representatives and issue a personal invitation to join us.

That same weekend, February 11, 1990, our popular Mid-Year meeting will take place at the Annapolis Ramada Hotel from 8:30 a.m. to 4:00 p.m. Drs.' Gossel and Wuest will present ''New Drugs and Therapies: 1990,'' a 5.5 credit continuing education program. Last year, 160 pharmacists turned out for this program so register early to take advantage of the lowest rates.

I am pleased and proud to bring this report to you. MPhA is well positioned to stand tall in the new year. On behalf of myself, the officers, trustees, and staff I wish you a healthy and prosperous 1990.

Nathaniel Futeral, P.D.

MPhA President

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Advising Consumers on OTC Analgesics: Acetaminophen

by **J. Richard Wuest, R.Ph., Pharm.D.**
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to:

1. describe the physiologic mechanisms of pain perception and pharmacologic action of OTC analgesics;
2. discuss the pharmacologic, toxicologic and therapeutic uses for acetaminophen; and
3. list specific patient information on methods to maximize acetaminophen's efficacy and minimize adverse effects.

in the service of pharmacy

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Gossel

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Objectives

At the conclusion of this lesson, the participant will be able to:

1. determine the physiologic mechanism of pain perception;
2. demonstrate an understanding of the pharmacologic and toxicologic mechanisms, and warnings and precautions for acetaminophen;
3. identify specific therapeutic uses and indications for acetaminophen; and
4. choose from a list, specific points for advising consumers on the correct use of acetaminophen.

There are currently three active ingredients comprising OTC analgesics: acetaminophen, aspirin and ibuprofen. They are commercially available in single-entity products indicated for relief of pain and fever. Acetaminophen and aspirin are also included in combination with other ingredients for treatment of these symptoms associated with the common cold.

In this article, topics include the phenomenon of pain and fever, activity of drugs in alleviating them, proposed theories on the pharmacologic and toxicologic actions of acetaminophen, and patient advice to pass on to consumers.

Fever

The normal body temperature is 98.6° F with a range of 96.5° F to 99.0° F. There is also a diurnal variation in body temperature, with the high point peaking between 3:00 and 5:00 p.m., and the low point between 3:00 and 5:00 a.m. Ovulation, overeating, overdressing on a hot day, and strenuous exercise can raise the body temperature without illness. Certain medications, such as oral contraceptives and antibiotics, may elevate the temperature by a degree. When this occurs, it usually happens during the second week of therapy.

Fever represents the body's natural response to certain illness. Elevated temperatures are inhospitable to microbes, and may help stimulate the body's immune response.

It is best to take a patient's temperature at the same time each day. Slight variations from the normal should be expected. The temperature should not be taken for at least 30 minutes after eating anything hot or cold, or after smoking or brushing the teeth. Fever that persists for longer than three days may represent a serious disease, and the patient should be referred to a physician.

What is Self-Medicatable Pain?

Pain is reportedly the most common symptom for which people seek relief. It is a protective mechanism which signals that something in the body is not functioning properly. Needless to say, it is best to first determine the cause of pain, and then treat the underlying disease process.

Mild to moderate pain that is temporary and self-limiting may be treated symptomatically by self-medication. But when pain persists longer than 10 days, continues to worsen with therapy, or is particularly severe, the affected person should seek medical assistance. It may signal the presence of a serious disorder.

When the FDA Advisory Review

Panel on OTC Internal Analgesics and Antirheumatic Products reviewed the vast literature on nonprescription analgesics, it concluded that the drugs are safe and effective for use in treating symptoms of occasional, minor aches and pains.

Minor pain, for the purpose of self-medication, is defined as that which is temporary and requires no special treatment or prior diagnosis. It is usually described as mild to moderate, as opposed to sharp, severe and/or protracted. Though no medical treatment is required for minor aches and pains, analgesics may be used to reduce their intensity and provide relief and comfort to the sufferer. These agents may make it possible for some individuals to maintain normal daily activities.

Frequent headache, joint pain which flares periodically, or lower back pain which comes and goes may suggest pathologic etiology. These should not be routinely treated with OTC analgesics except on the advice and supervision of a physician.

Analgesic Classification

Analgesics indicated for mild pain are chemically divided into two main subgroups: centrally acting and peripherally acting. The former includes agents structurally related to narcotics such as codeine and propoxyphene. Peripherally acting analgesics also exert antipyretic and anti-inflammatory, or possibly antirheumatic, activity. This latter group includes acetaminophen, salicylates and the other nonsteroidal anti-inflammatory drugs (NSAIDs). At the time of publication of this article, ibuprofen is the only non-salicylate NSAID available OTC. Others will follow in the near future.

The nonprescription agents are not as potent for relieving moderate pain as the stronger prescription-only analgesics. But they are effective for their labeled indications.

Pain that responds to OTC analgesics is generally characterized as relatively low intensity. These include headache, muscle pain (myalgia), joint pain (arthralgia), and other discomfort arising from trauma or skin irritation.

Mechanism of Action of OTC Analgesic/Anti-Inflammatory Agents

OTC analgesics are theorized to relieve pain principally by a peripheral action which blocks impulse generation of pain fibers entering the brain. They do not appear to exert overt central activity as do the narcotics. However, their antipyretic (fever reducing) effect seems to be due to central action in the hypothalamus.

In spite of their long history of use, the exact mechanism of action of OTC analgesics has not been identified. The current theory is that they interfere with prostaglandin synthesis. Acetaminophen has a more modest inhibitory action than NSAIDs.

Prostaglandins are produced in all cells. They exert profound physiologic actions in low, even molecular concentrations. Produced in response to trauma and other noxious stimuli, they are involved in the inflammatory response, including alerting the body of a problem, i.e., pain. Some of the physiologic responses for which prostaglandins are implicated respond to acetaminophen therapy. These include pain, fever and dysmenorrhea. The role of prostaglandins in causing pain will be elaborated on in a future article.

Acetaminophen may also inhibit synthesis or action of other (as yet unidentified) substances which sensitize pain receptors to mechanical or chemical stimulation.

Acetaminophen

Though the exact mechanism of action of acetaminophen has not been defined, the drug has been used extensively to treat pain and fever. It was first used in 1893, but did not become popular until the early 1950s.

It was shown in the late 1940s that both phenacetin and acetanilide, two drugs used for decades to relieve pain, were converted *in vivo* to their major metabolite, acetaminophen. With this discovery, acetaminophen use gained renewed popularity.

A major factor in the rapid rise of acetaminophen usage was the implication that phenacetin and acetanilide caused serious renal damage to far greater extent than acetaminophen. Over the years, acetaminophen-containing products have gained a sizeable share of the OTC analgesic market. In the meanwhile, both phenacetin and acetanilide have been removed from the North American market.

Acetaminophen is as effective as aspirin on a milligram-to-milligram basis for relieving pain of mild to moderate intensity and fever. Used as directed, it is also safe. Its lack of anti-inflammatory action makes it less useful in conditions such as rheumatoid arthritis. However, it may be used to relieve pain due to mild osteoarthritis.

Its use in treating pain and fever in children has now far exceeded that of aspirin. Acetaminophen is not implicated in causing or worsening Reye's syndrome. The association of aspirin to Reye's syndrome will be discussed in a future article.

Acetaminophen is almost completely and rapidly absorbed from the gastrointestinal tract. Following administration, peak plasma concentration occurs in 30 to 60 minutes. The drug is uniformly distributed throughout most body fluids. Its half-life is 2 to 2.5 hours. It is metabolized in the liver, and it's metabolites are readily excreted. There is no evidence that it accumulates in body tissues when taken at recommended doses.

Acetaminophen, like other antipyretics, lowers body temperature in patients with fever, but does not reduce it lower than normal. Body temperature regulation is controlled to a large extent by the hypothalamus. During fever, the balance between heat production and heat loss continues to be regulated by the hypothalamus, but the body temperature is set at a higher than normal level.

It is reported that a temperature in the range of 103° F will be reduced by 2 to 3 degrees within 3 to 4 hours of acetaminophen administration (the same is true for aspirin). Then, following a plateau, the temperature increases gradually. As a general rule, antipyretic therapy is not intended to bring the temperature completely back to normal, but to make the patient more comfortable.

When consumers purchase an acetaminophen-containing product, pharmacists should explain the

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Table 1

Pediatric Dosing Schedule for Acetaminophen

Age (years)	Dose (mg)*
0-3 mo	40
4-11 mo	80
1-2	120
2-3	160
4-5	240
6-8	320
9-10	400
11	480

*May be repeated 4-5 times daily; not more often than 5 doses/24 hours.

proper use of the product. A 1984 editorial in the journal *Pediatrics* stated that some people were unaware of a difference in concentration of acetaminophen *elixir* and *drop* dosage forms. Specifically, parents were using the enclosed dropper from the drop dosage form with its metric dosage recommendation, to administer the elixir. This error led to failure in controlling fever because of inadequate dosage. The authors reported that, in some cases, the motivation for this change in medication appeared to be economic; the more concentrated drop form was five times more expensive than the elixir. In other cases, parents were simply unaware of either the differences in concentration, or the metric equivalents of dropper markings compared to a teaspoon measure.

The total daily dose should not exceed 1.3 gm daily in any child, and should be decreased proportionately in younger children. Although package labels indicate that acetaminophen is not to be used longer than 10 days, this time frame relates to its analgesic use. Used for antipyresis, the drug should be limited to three days. A pediatric dosing schedule for acetaminophen is presented in Table 1.

How Safe is Acetaminophen?

Acetaminophen is safe when used as directed. Taken in recommended doses, it is relatively free of adverse effects in most age groups, even in the presence of a variety of disease states. Unlike aspirin, it does not increase fecal blood loss, cause mucous membrane reactions in patients with gastrointestinal illness, interfere with the action of uricosuric drugs or cause adverse effects on clotting mechanisms in hemophiliacs.

However, several studies have demonstrated small increases in the blood clotting time in patients using acetaminophen. Large doses have shown that a mild methemoglobinemia (oxidized hemoglobin that does not transport oxygen properly) occurs.

A few cases of hypersensitivity have been reported. These are manifested by skin rash and thrombocytopenic purpura (characterized by black and blue patches on the skin and mucous membranes). Rarely, hemolytic anemia (erythrocyte destruction) and/or a serious blood dyscrasia — agranulocytosis (reduced levels of neutrophils and leukocytes — two types of white blood cells) occur.

The only known contraindication to the use of acetaminophen is well-established hypersensitivity to the drug. Care must be taken to assure that a hypersensitive individual does not unknowingly purchase an acetaminophen-containing combination product. Persons who are sensitive to aspirin or ibuprofen can generally take acetaminophen without problem.

Definitive studies are not yet available on whether acetaminophen should be used in patients with preexisting liver disease. Evidence suggests that, in some forms of liver disease, there is decreased conjugation (metabolism) of the drug with an increase in its half-life. This is perhaps significant in toxic reactions to overdoses. For this reason, OTC products containing acetaminophen must display the warning on their label, "Do not exceed recommended dosage because severe liver damage may occur."

Drug Interactions

There does not appear to be any overtly significant drug interactions involving acetaminophen. Drugs which cause liver damage or induce hepatic enzyme production (e.g., phenobarbital, phenytoin, rifampin) may enhance acetaminophen-induced hepatic toxicity, or metabolism of acetaminophen into its toxic metabolite.

It has been reported that chronic use of high doses (greater than 3 gm daily) of acetaminophen may increase the anticoagulant effects of warfarin, possibly by decreasing hepatic synthesis of precoagulation factors. The clinical significance of this interaction has not been established.

There is a report of interaction between acetaminophen and zidovudine (Retrovir®). Acetaminophen may competitively inhibit metabolism and decrease clearance of zidovudine from the body, thus increasing its toxicity. The same is true of aspirin; there is no information on

Table 2

Clinical Stages of Acetaminophen Poisoning

Stage	Clinical Characteristics
I (within 24 hr)	Abdominal pain Anorexia, nausea, vomiting Drowsiness Malaise Sweating
II (24-48 hr)	Period of "apparent recovery" Patient feels better Hepatic necrosis begins Urine output slightly decreased
III (3-5 days)	Marked hepatotoxicity Jaundice Coagulation defects Hypoglycemia Hepatic encephalopathy Renal failure Coma Death

ibuprofen. Because of the toxicity potential of zidovudine and the medical seriousness of AIDS, patients on zidovudine therapy should not self-medicate with OTC analgesics without consulting with their physician.

Acetaminophen Toxicity

It was only recently recognized that acetaminophen can cause serious poisoning. Unfortunately, it does not cause an early neurological warning sign of toxicity as does aspirin, i.e., tinnitus. Acetaminophen poisoning is potentially much more serious and lethal than aspirin toxicity because of this.

Table 2 shows the various stages of acetaminophen poisoning. Initially, symptoms such as gastrointestinal distress lessen with time and the individual feels better. If the proper antidoting protocol is not performed early in the course of poisoning, liver damage may occur. Within 2 to 3 days, the damage may be irreversible. Hepatic necrosis is the most serious and devastating toxic effect.

Figure 1 traces the metabolism reactions of acetaminophen in the liver. Metabolism is accomplished primarily by conjugation of acetaminophen with glucuronide and sulfate as noted at the top of the figure. Another pathway, which is normally of minor importance, involves formation of a highly reactive and harmful intermediate metabolite. Less than four percent of a therapeutic dose of acetaminophen is normally metabolized by the enzyme cytochrome P_{450} mixed-function oxidase. The resulting metabolite then reacts with proteins within the hepatic cells leading to cellular necrosis. When acetaminophen is taken in therapeutic doses, glutathione, an amino acid also present within the liver cells, reacts with the small quantity of toxic metabolite to form a nontoxic substance and prevent the damaging reactions.

When an overdose (10 to 15 gm for adults; 4 gm or less for children) of acetaminophen is ingested, the liver's enzyme system becomes saturated. The supply of glutathione is inadequate to meet the needs of inactivation of the massive quantity of toxic metabolite being formed. This binds with the hepatic cell proteins, and causes their destruction. The result is the liver damage mentioned earlier.

Treatment of Acetaminophen Poisoning. As soon as poisoning has occurred, the victim should be given ipecac syrup to induce vomiting (after having been instructed to do so by a physician or poison control center). Acetylcysteine (e.g., Mucomyst), given orally, is the specific antidote for acetaminophen poisoning and must be initiated quickly after emesis has been induced. Acetylcysteine enhances synthesis of glutathione and provides free sulfhydryl groups for the toxic metabolite to bind with, thus preventing it from damaging the liver cells. Furthermore, acetylcysteine serves as a source of sulfur to enhance acetaminophen metabolism along its sulfate route, decreasing the amount of drug that would be metabolized by the cytochrome P_{450} system. With acetaminophen overdose, the use of activated charcoal is not recommended since it may interfere with absorption of acetylcysteine.

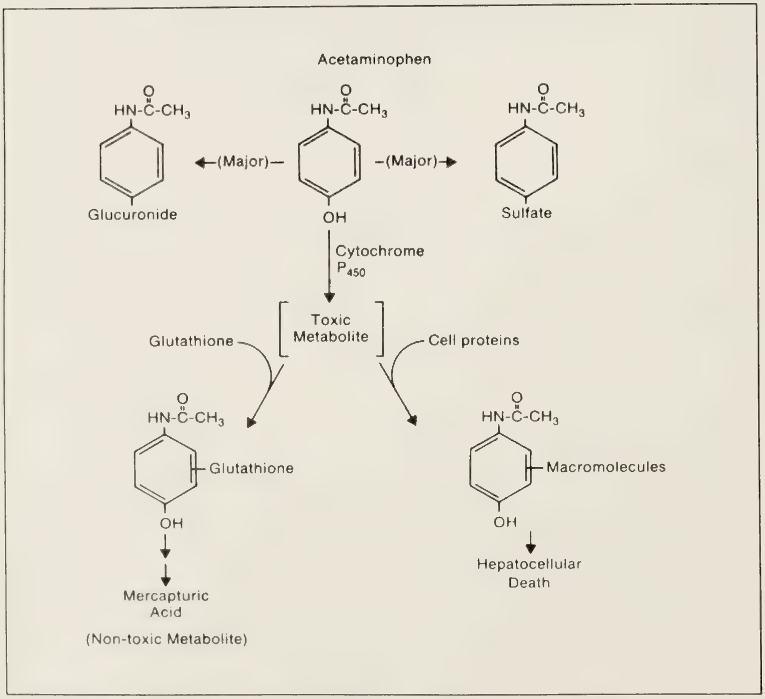


Figure 1. Scheme for acetaminophen metabolism. From *Principles of Clinical Toxicology*, 1984, Raven Press.

Summary

Acetaminophen is a safe and effective drug for self-treatment of minor pain, fever and dysmenorrhea, when used correctly. Consumer advice is included in Table 3.

Table 3

Consumer Advice for Acetaminophen
•Do not take this drug for longer than 10 days for pain, or 3 days for fever.
•For children under 12 years of age, do not give this product for longer than 5 days for pain.
•Do not exceed the recommended dosage because severe liver damage may occur.
•Keep this and all drugs out of the reach of children. In case of accidental overdose, contact a doctor or poison control center immediately.

The Kinnard Years

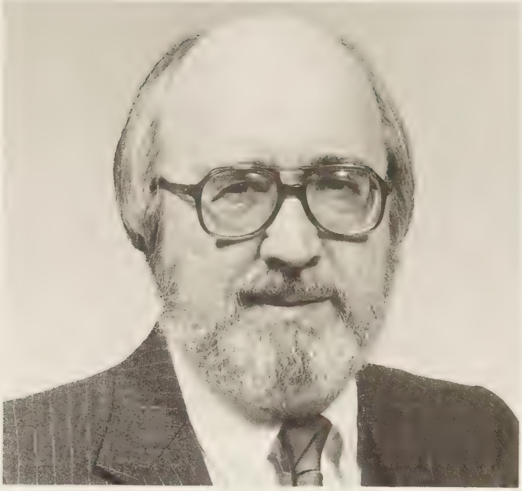
1968–1989

In 1968, when William J. Kinnard, Jr. came to the University of Maryland as one of the youngest men ever to serve as a dean of a School of Pharmacy, he could not have imagined all of the changes he would see in both the profession and the school or the important role he would play in these events. However, during the next 21 years, Dr. Kinnard was to have an impact on virtually every aspect of pharmacy in Maryland and in the nation.

Improving Professional Pharmacy Education

Dr. Kinnard received his pharmacy degree and masters from the University of Pittsburgh and doctorate in pharmacology from Purdue University. He directed his earliest initiatives to refining, improving and expanding the undergraduate professional education programs offered by the University of Maryland School of Pharmacy. When he came to Maryland as dean in 1968, the school had a total of 123 professional students in its three year program, 12 graduate students, and a faculty of 21. Its five departments were: pharmacy, pharmaceutical chemistry, pharmacology, pharmacognosy and pharmacy administration. Over the next two decades, the school was to play a major role in reshaping the profession through increased emphasis on the innovative professional and service programs as well as through the recognition of the clinical role of pharmacists in all practice settings.

Redefining Professional Education



William Kinnard, Ph.D.
Dean, University of Maryland School of Pharmacy
1968–1989

Dr. Kinnard's role as an administrator who stimulated and nurtured faculty initiatives is nowhere more apparent than in the development and implementation of the Professional Experience Program (PEP). This practice-based educational model was to revolutionize modern pharmacy education on a national level. Interacting with the Maryland Board of Pharmacy and the state professional associations, Dr. Kinnard, with Dr. Ralph F. Shangraw and the department of pharmacy, created a curriculum that incorporated actual pharmacy practice experience. Students in their senior year would be assigned to a variety of practice sites and work with an approved practitioner who had adjunct faculty status. The school, which closely monitored these practice sites, gave academic credit for the successful completion of each rotation. This not only provided a hands-on approach to pharmacy education but allowed students to experience a variety of practice situations. The Maryland Board of Pharmacy has accepted this supervised training as a prerequisite for licensure replacing the mandatory internship. Today the professional experience program is the national model for professional pharmacy education.

Innovative Statewide Programs

Encouraging innovative statewide service programs was another hallmark of the Kinnard years at Maryland. From the beginning, Dr. Kinnard recognized the crucial role that pharmacists should play in providing both drug information and drug abuse education.

An early approach to incorporate drug abuse education into the school's curriculum resulted in the student-led Student Committee on Drug Abuse Education (SCODAE). Today SCODAE is part of the larger Office of Substance Abuse Studies, under the direction of Anthony C. Tommasello, MS Pharm., which provides information on drugs of abuse via the telephone, face to face programming and a national newsletter, PharmAlert. SCODAE continues to offer a five-day program given by pharmacy students to middle, junior and high school students and in-service programs for educators and health professionals. A recent $220,000 two year grant from the Fund for the Improvement of Post Secondary Education has allowed SCODAE to replicate its program in other Schools of Pharmacy nationally. For several years the school operated the Anonymous Drug Testing Laboratory to assay street drugs in an attempt to provide better information to the public, health professionals and law enforcement officials regarding what drugs were available on the street and how dangerous they were. SCODAE would help disseminate this information to drug abuse hotlines and others in an effort to provide accurate drug information and prevent overdoses.

Another innovative service program begun during the Kinnard years was Elder-Ed, a geriatric pharmacy education program developed by Dr. Peter P. Lamy which teams pharmacy students with retired pharmacists to provide programs on medication management for the elderly. Elder-Ed, which is underwritten by a grant from Parke-Davis, produces a national newsletter, Elder Health News, for pharmacy practitioners. Over the past six years, Parke-Davis has provided over a half a million dollars in support of this program.

In 1972 the state's central poison information center was moved to the School of Pharmacy from Baltimore City Hospitals. This move reaffirmed the role of pharmacists as drug information specialists. Today Gary M. Oderda, Pharm.D. directs the Maryland Poison Center, an accredited regional poison center of the American Association of Poison Control Center (AAPCC), which handles 50,000 emergency telephone calls annually. Staffed by pharmacists and registered nurses, the Maryland Poison Center provides 24-hour emergency telephone information on potential poisons to the general public and health care-providers. Its educational programs include public and professional in-service and poison prevention programs as well as a quarterly newsletter, Toxalert.

Expanding Research Initiatives

If the school's educational and service programs were the focus of the late sixties and early seventies, Dr. Kinnard brought its research initiatives to the fore in the eighties. The completion and occupation of Pharmacy Hall in 1982 led the way for the expansion of school's basic science research projects. The unique design of the building offers a central core of laboratories with faculty offices located conveniently across the hall. Modern, sophisticated instrumentation, including mass spectrometry the Nuclear Magnetic Resonance (NMR) and the molecular modeling workstation, has enhanced the school's interdisciplinary research activities as well as its ability to obtain grants and contracts. The expansion of the school's research initiatives has produced a corresponding increase in graduate education programs. Currently the school has 75 students pursuing masters or doctoral degrees.

Exerting a National Influence

In recent years the school, under Dr. Kinnard, has focused on national issues impacting in pharmacy

'Tween Scripts

By Jake Miller
Pharmacist

Honoring Pharmacy's "Extra Effort" People

Again this fall, current year recipients of the A. H. Robins "Bowl of Hygeia" Award, selected by their peers through their professional pharmacy associations in the 50 states, the District of Columbia, Puerto Rico, and the 10 Canadian provinces were invited to be guests of our company for a special salute in our Richmond headquarters.

The four-day event included receptions and dinners, tours of our manufacturing and research facilities and a sightseeing trip to Williamsburg, the restored colonial capital of Virginia.

It was a desire to encourage pharmacists to take more active roles in community affairs that prompted E. Claiborne Robins, chairman of the board of A. H. Robins Company and a pharmacist himself, to establish the "Bowl of Hygeia" Award in 1958. The award provides special recognition to the men and women of pharmacy for their many and varied community services.

Some have served in their state legislatures and on city councils. Others have filled important positions on planning and zoning commissions and hospital, school and other boards. They have provided leadership for fund drives and countless special projects, and have participated in the work of youth organizations, civic clubs, churches and fraternal organizations. Perhaps a quarter of the over 1,800 recipients thus far have headed their state or provincial pharmaceutical associations at one time or another.

The award is a handsome plaque featuring the Bowl of Hygeia cast in bronze. So that they may be recognized wherever they go, award winners are also presented lapel pins which are scale replicas of the plaque, and at any gathering of pharmacists, those wearing the pin form a proud "alumni" of previous recipients.

A. H. Robins is pleased to be able to assist state and provincial associations in recognizing these "extra effort pharmacists."

Jake Miller

A·H·ROBINS

A. H. Robins Company
Richmond, Virginia 23220

through two national multi-disciplinary centers of social research: The Center on Drugs and Public Policy and The Center for the Study of Pharmacy and Therapeutics in the Elderly. Both centers incorporate education, research and service components. The Center for the Study of Pharmacy and Therapeutics in the Elderly, led by Dr. Peter P. Lamy, supports a wide range of projects from basic research into developing drug dosage forms for the elderly to providing medication management education programs for caregivers, those who care for the non-institutionalized elderly. The Center for Drugs and Public Policy, a joint initiative of the school of pharmacy and the policy sciences graduate program at the University of Maryland Baltimore County and directed by Dr. David A. Knapp, focuses on national drug use policy issues such as the role of pharmacy technicians and provides consultative services and technical support to industry and government agencies such as HCFA.

Expanding Corporate and Private Support

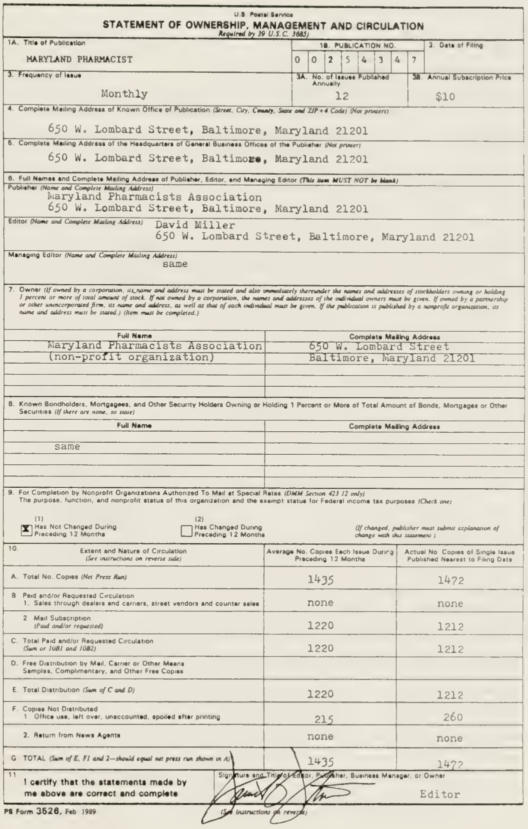
During his tenure, Dr. Kinnard has worked diligently on behalf of the School of Pharmacy was to increase its corporate and private support. In 1984 Dr. Kinnard named the school's first Board of Visitors, a prestigious advisory council of state and national pharmacy and corporate leaders who provide input on the School's programs and initiatives. To increase support for many ventures unfunded in the state budget, Dr. Kinnard established the David Stewart Associates, the school's chapter of the University's Presidents Club. Today the David Stewart Associates has 53 members who have paid or pledged at least $10,000 to the school. Dr. Kinnard's most recent development efforts have been directed to obtaining major gifts for the school in conjunction with the University's $200 million capital Campaign for Maryland.

Commitment to the Profession

As Dr. Kinnard leaves the School of Pharmacy to serve as Acting President of the University of Maryland at Baltimore (UMAB), he leaves a legacy of commitment to the profession that has expressed itself in actions not words. The school, which has a first year class of over 100 students, now graduates 80–90 students in its bachelor of pharmacy program and 12–15 doctor of pharmacy students annually. Its 56 full-time faculty members are actively engaged in conducting a variety of education, research and service programs that have achieved state and national recognition and many of these initiatives are fully funded by state or private support.

Dr. Kinnard's work on a national level has included many major roles in national professional pharmacy associations. He served as the President of the American Association of Colleges of Pharmacy during 1976–77, as one of the first two pharmacists elected as a member of the Institute of Medicine of the National Academy of Sciences, as Scholar-in-Residence at the American Association of Colleges of Pharmacy 1988–89 and as the national civilian consultant on pharmacy to the Surgeon-General of the Air Force since 1983. Dr. Kinnard was the Chairman of the Board of Trustees of the United States Pharmacopeial Convention from 1975–1985.

As the school conducts a national search for a new dean, it does so with the knowledge that the Kinnard years have increased the stature and prestige of the institution making it among the best in the nation.



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Commentary

Dickinson's Pharmacy

Jim Dickinson

Letter to Rite Aid. The biggest chain in pharmacy has done an amazing thing—it has become lovable while "acquiring" its way to the top.

Rite Aid has done this by simply holding press conferences that tell the world out loud what all the rest of pharmacy has been muttering under its breath for decades: "No more Mister Nice Guy—pay me enough to live on, or take your business elsewhere."

While it's fair to say that when you get to be as big as Rite Aid is, you can afford to talk tough—and who else is that big and that tough?—it's also fair to ask Rite Aid if it really means what it says.

So here's an open letter to Rite Aid CEO Alex Grass, who as a hard-headed businessman doesn't care whether he's lovable or not.

Dear Alex:

There's no doubt that you're to be congratulated for becoming the biggest drug chain and for standing up to the financially unrealistic third-party programs who try to make pharmacies run at a loss. If you'd kept Rite Aid a little smaller by not eating up markets that sustain uneconomic little independents, then you might never have become big enough to say what needed to be said.

Those small pharmacy businesses, by simply being there for somebody like Rite Aid to come along and get, ended up involuntarily doing you good, and helping you deliver the message that needed for so long to be heard.

In fact, many of those nervous little pharmacies went out of business for the very reason that you're now being heard to tell about so boldly—their third-party customers didn't pay them enough to make a living.

You're singing *their* song. After they've gone.

If it had been heeded before you came along, they might still be here.

I saw you last night on CNN, being interviewed by Myron Kandel and two business editors. When you were asked who was to blame for the generic drug scandal, you begged off, saying, "I really haven't studied that too much."

I suppose you haven't "studied" Rite Aid's impact on the independent pharmacy too much, either. But I hope you will make yourself more familiar with both subjects, for the good of the hands that feed Rite Aid as it tries to develop even more.

A loss of public confidence in generic drugs, caused by the idea that FDA somehow "sold" second-rate approvals to schlock houses for a while, would hurt everybody—especially the biggest pharmacy chain in the country, which has more to lose. You should be helping your people tell everybody whose fault that episode was, and in so doing help confine it and put it behind you (and all of us).

And you should be looking at the communities that are suddenly left without a pharmacy, due to past Rite Aid acquisitions. That way, you could try more seriously to grow in ways that might not hurt others.

In the TV interview, you criticized brand-name drug manufacturers by saying that perhaps some of them didn't need to make *quite* so much money on their new drugs. Perhaps they could let life-saving new therapies like AZT out for a little less off the top?

And, equally, might Rite Aid not make *quite* so much money for its stockholders in some of its acquisition and growth projects? Perhaps by protecting vulnerable communities with such services as home delivery and pharmacy time for free counseling (not just a binder hanging on a chain at the prescription counter), Rite Aid might make a little less off the top—but more over the long run? You're right, of course. I don't know how to run Rite Aid better than you do.

But quite a few people think that when you get to be the biggest of anything, when you really can get to throw your weight around, you need to be especially sensitive, and to "study" on things you might not have bothered about before.

Hardly anybody ever does, when they get that big, however. It seems to go to their heads. And sometimes then they crash.

Just a thought, Alex.

This feature is presented on a grant from "Dickinson's Pharmacy—The Independent Voice," an 8-page practical monthly newsletter available from Ferdic, Inc., P.O. Box 848, Morgantown, WV 26507-0848 at an annual subscription fee of $45.

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This And That About Pharmacy

Leon Weiner, P.D.

Brief News

Thomas Dale Wieland ('84) opened up his Medicine Shoppe in Glen Burnie, MD shortly after graduation. He and his wife, Monica, have 2 children, Erika, 7 months and Jeremy, 3 years old. Tom got his first degree in 1976 in biochemistry and worked as an analytical chemist for the Department of Defense at Walter Reed Army Institute of Research. Because he resides so close to his store, he often rides his bike to the pharmacy.

Mark E. Hawes ('76) is currently a pharmacy supervisor for Weis Markets, IN.

Allen and Victoria Karpe are very proud to be the parents of their first daughter, Sarah Alexandra Karpe who arrived February 9, 1989. Allen ('83) works for Valu Drug Company and lives in Columbia, Maryland.

Susanna Peters Gutberlet ('73) is now a multi-million dollar sales associate with Caldwell Banker. She was a former owner of Hereford Pharmacy.

Marge ('47) and Howard Surell ('47), were observed recently at the American Society of Italians and Friends dinner aboard the Bay Lady.

Michael Wittelt ('80) became a partner/owner of Tenley Pharmacy in Rockville, MD in 1985. As a sideline, Mike is the assistant coach of the Mason-Dixon Volleyball Club Jr. Olympia Girls team. This team practices at Laurel High School and plays volleyball games all over the East Coast.

Ronald A. Keech ('77) has been employed at The Apothecary, in Bethesda, MD since he graduated. He and his wife were married in 1985 and are the parents of a two year old son, Aubrey. They expect to become parents again very soon.

Here's wishing a complete recovery to Eugene Streett, the son of Mechem E. Streett ('52) of Boyd and Fulford Pharmacy in Bel Air, MD. The younger Streett was severely injured in a motorcycle accident in April of last year.

Congratulations to Stanley B. Tannebaum ('66) on his promotion to Division Manager of the Washington, Virginia, and Maryland areas. Also to Marvin Jaslow ('58) on his promotion to Director of Professional Placement. Both Marv and Stan are employees of Rite Aid.

If you are interested in a Korean Pharmacy Association in Maryland, contact Amanda Yoo Pak ('82) at 301-345-4700 or at Hollywood Drugs, 10001 Rhode Island Avenue, College Park, Maryland 20740.

David ('54) and Ruth Greenfeld own Woodlawn Pharmacy in Baltimore County. Their daughter, Susan Greenfeld Eichner, graduated from the school of pharmacy at the Medical College of Virginia in 1982. She is now the manager of the pharmacy at Weis Food Market at Owings Mill, MD.

Jacqueline Collins Touse ('83) has been employed by Giant Drug Company for the last 4 years. Her husband, Rob, is a builder in Columbia, MD and they have one son, Matthew, who is one year old.

Allen F. Novak ('80) is employed at ComputeRx of Glen Allen, Virginia. If you have any questions, call him at 1-800-368-2153.

Herbert J. Burns, Jr. ('53) has been a pharmacist/partner at the Howard and Morris Pharmacy, Rolling Road, for many years. He married Peggy Lotz in 1955 and they have three children, all active in pharmacy. For many years Peg has been working at the drug store with her husband. Their oldest daughter, Susan Burns Zins is a drug buyer at Baltimore County General Hospital. Next in line is son Michael Burns ('88) who works at the Columbia Medical Plan Pharmacy and does some part time work for his dad. Their youngest daughter has finished up the third year in the UMAB Pharmacy School. Herb and Peg are very proud of their pharmacy family.

Donald M. Kirson ('70) is the president and founder of the Kirson Medical Equipment Company, the nation's first independent home medical equipment supplier to be approved by the Joint Commission on Accreditation of Health Care Organizations. The Baltimore company has branch offices in Beltsville and New Jersey. Don is the son of Jerome Kirson ('33).

In a feature story in the Sun Papers, Charles Alpert ('67), owner of Alpert's Pharmacy, and many of his employees were presented as godsends to 86 year old Foster Cone. They and others nursed him back to health.

Congratulations to Clayton Warrington ('58) on being selected as the Alumni Association 1989 Honored Alumni Award. He was honored on May 25, 1989 at the Pharmacy School Graduation banquet.

Congratulations to Mark Levi ('70) who is the new President Elect of the Maryland Pharmacists Association for 1989–1990. Levi is a partner/owner of a number of pharmacies in the Baltimore area.

Congratulations to Thomas (Tony) W. Kearney ('71) who was recently promoted to supervisor by Giant Drug Company. He is a past employee of Read Drugs and Rite Aid.

Congratulations to Dr. Matthew G. Shimoda ('84) and wife Donna on the birth of their second child Adam Jared, 7 lbs. 15 oz. on May 18, 1989. They also have a little girl, Jessica, who is 3 years old. Matthew is a partner/owner of several pharmacies in Anne Arundel County.

Congratulations to Debbie ('84) and Murray A. Mease ('84) on the birth of their first child, Matthew Logan Mease 7 lbs. 3¼ oz. on May 22, 1989. Proud grandparents are Sydney and Harry Bass ('58) and Mr. and Mrs. Alan Mease of Cumberland, MD.

A former Drug Fair employee, Carol Majdanski Sobon, ('78), now works for Giant Drug Company and resides in Columbia, MD.

Kathryn L. Parker ('85) opened up the Arnold Professional Pharmacy, Inc. in January 1989. Previously, she had worked for People's Drug and Giant Pharmacy. Kathy's dad is a pharmacist owner in Elk Rapids, Michigan and her husband is a airline pilot for one of the major airlines.

Melvin "Marsh" Friedman ('58) is now the owner of Shoreline Board Shop in Ocean City. He was the previous owner of Linden Pharmacy. The Shoreline Board Shop specializes in all types of boogie boards designed to give bodyboard enthusiasts the edge they need to rip and carve the Atlantic waves.

Recently the son and daughter-in-law of Drug Inspector William A. Hahn ('49) have been very active in the news spotlight. William A. Hahn, Jr. is an attorney who was involved in the large Aberdeen Hazardous Waste Trial. He also is the president and executive director of the Baltimore Yacht Association and participated in their awards banquet at the Governor's Club. His wife, Sharon Hahn, was the chairperson for the League for the Handicapped's LeGala, which was held recently at the Stouffer Harbor Place Hotel. In addition, both William and Sharon attended the black tie preview party to kick off Benefete, an art show and sale to benefit the St. Paul's Choir of Men and Boys. William Jr. is also the brother of Jeffrey C. Hahn, University of Maryland School of Pharmacy gradutate of 1971, who is a pharmacist sales representative for Eli Lilly and Company.

James (Tim) Cragg ('43) and his wife Marie, ran the Irvington Rexall Pharmacy for more than 40 years until they retired in December 1988. One of his Rexall Pharmacy signs was taken by the Smithsonian Institute in Washington, D.C. to fill a gap in the museum's collection.

Steven M. Simko ('71) now works for People's Drug Store in Lexington Park, MD. He was in the U.S. Army from 1971 to 1974 and was an instructor in Pharmacy at the Academy of Health Sciences at Ft. Sam Houston, Texas. In 1977, Delegate Roy Dyson chose Steve as one of the Outstanding Young Men of America. Dr. Simko resides in California, MD with his wife, Joan Helen.

After working with Giant Pharmacy for several years, Duncan Runyon ('82) has moved back home to the Eastern Shore. He will be working for Rite Aid.

Recent Pharmacy Passings

Alder Simon ('43) passed away on April 3, 1989. During his pharmacy career, Dr. Simon was active with 3 small drug chains. They were Sun Ray, Stofberg Drug and the Action Drug Groups. He also had owned several drug stores including Westview Pharmacy and Midway Pharmacy. Recently he has been employed at Spring Grove State Hospital Pharmacy. Alder is survived by his wife Pearl and two children.

Condolences to Sidney Zerwitz ('32) and his son Warren G. Zerwitz ('61) on the passing of their wife and mother, Lillian K. Zerwitz on May 17, 1989. Sid is a retired pharmacy owner and Warren works for K Mart Pharmacy on Liberty Road in Baltimore County.

Stephen Panamarow ('42) passed away November 16, 1988. Steve was a partner/owner of two drug stores in the Baltimore area. In 1967 he sold out his share of the stores to the present owners, Melvin Rubin and John J. Strauch. He then worked for Drug Fair and Rite Aid. Dr. Panamarow is survived by his wife Janet and two daughters.

Jerome Kirson ('33) passed away on June 17, 1989. He was a long time owner of Kirson Drug Company in Baltimore, MD. He is survived by his wife, Martha, 2 daughters and 2 sons including Donald M. Kirson ('65).

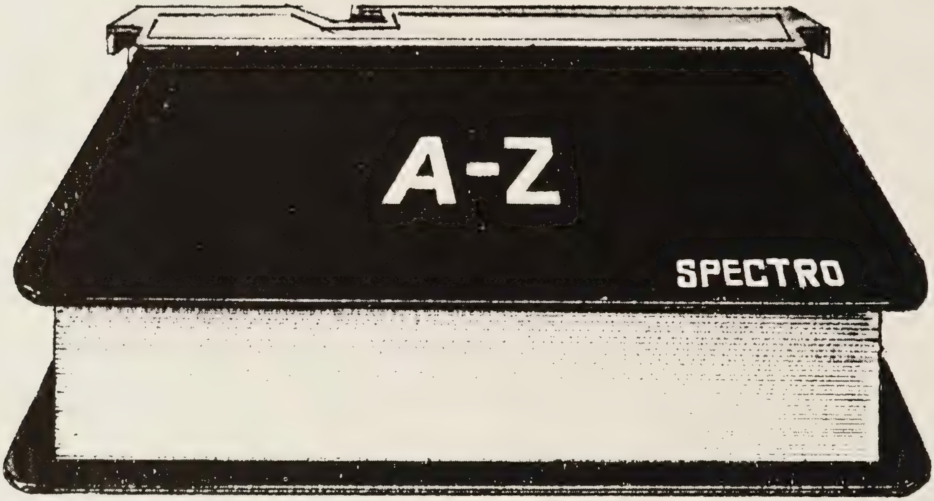
Milton H. Feldman ('32) passed away on April 22, 1989. He owned Regal Drug Store and the Reliance Drug Store. Milton was recently employed by the Rite Aid Drug Company.

Isadore Horwitz ('34) passed away May 8, 1989. He is survived by his wife, Dorothy, 2 sons and 3 grandchildren. Isadore operated the Smallwood Pharmacy at Smallwood and Presbury Streets in Baltimore City. Since closing that store, he has worked at the City Jail Pharmacy, North Charles General Hospital, Clifton T. Perkins Pharmacy, and recently at the Rosewood State Center.

Louis T. Sabatino ('39) passed away on March 25, 1989. He was a graduate of Forest Park High School. From graduation to 1947, he worked for Parkville Pharmacy. In 1947, Lou and his pharmacist classmate, Albert Binstock, became partners in the Woodside Pharmacy until 1965. He continued to work part-time for Alameda Pharmacy and also became a Drug Inspector for the Division of Drug Control. Dr. Sabatino was active in the Wedgewood Club, the Baltimore Veteran Druggists' Association and the Heritage Club of the University of Maryland. Lou was always a hard working sincere person with a keen sense of humor and devoted family man.

Joseph L. Combs ('38) passed away March 17, 1989 in Florida. After Pharmacy School, Joe worked for Read Drug and Chemical Company for several years. He then became a partner/owner of Combs Neutze Pharmacy on York Road. After leaving this store in 1961, Dr. Combs moved to St. Michaels on the Eastern Shore and opened a pharmacy there in 1962. He then moved to Seminole, Florida. While there, he worked for Walgreens Pharmacy for several years. Dr. Combs is survived by his second wife, Helen Walls Combs and several children.

22,000 Items.
Now that's healthy!



You'll find in this book the most comprehensive listing of items available to your pharmacy. You'll also find we can deliver everything we list and do it within 24 hours.

This book is only Volume One in our library. Sales ideas, pricing, services, and time saving procedures, are all contained in the table of contents. Please call us.

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Landover, MD 20785 301-322-1100

Loewy Drug Co., Inc.
Baltimore, MD 21237 301-485-8100

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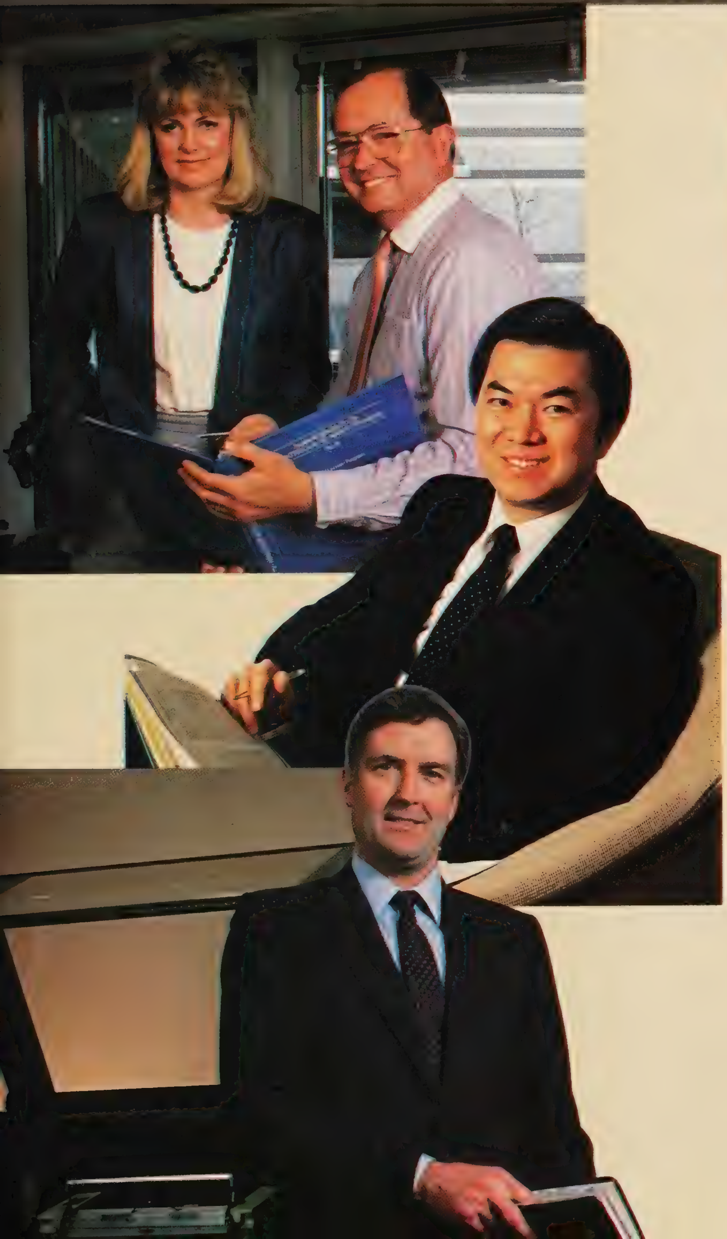

At Boehringer Ingelheim Pharmaceuticals, Inc., the Department of Medical Affairs demands the best and brightest in the industry.

Led by William Wardell, MD, PhD, Vice President, Medical Director (below, left), the group is made up of physicians and specialists in various medically related fields.

People like Thomas Chin, PharmD, Manager, Medical Information Services (center), Laura McGuire, RN, Assistant Director, Clinical Investigation (above, right), and Kathryn Riccio, Manager, Medical Education and John Elliott, RPh, Manager, Conventions and Scientific Exhibits (above, left).

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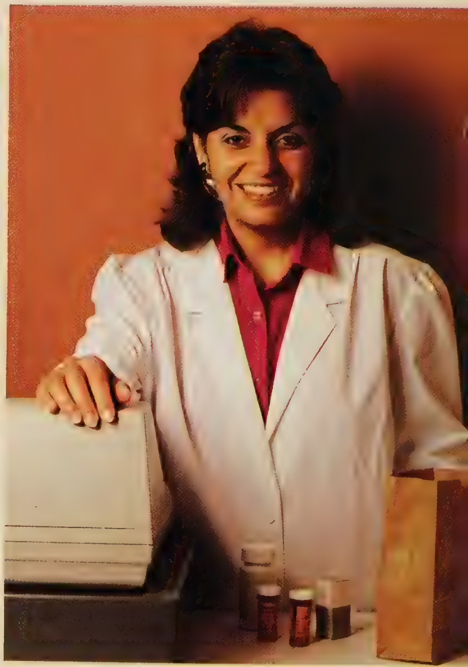

MI-4192

Benjamin Samuel Levin ('38) passed away on February 24, 1989. After graduation, Ben worked several years for Reads and then at Purex Corp. in Washington, D.C. He then served in the Armed Forces during World War II. After discharge, he worked for Libby Drug Store, Bell Drug Company, and then opened up Richard's Pharmacy on Eastern Avenue in 1957 and remained there until 1973. Dr. Levin worked full-time for Lutheran Hospital Pharmacy and he retired in 1980. Among his survivors are his wife, Shirley, 2 children, 1 brother, and sister Evelyn Levin Yerzeroff and brother-in-law, Benjamin Yerzeroff, both graduates of the University of Maryland School of Pharmacy in 1943.

Louis E. Oken, ('32) passed away on February 26, 1989. He is survived by his wife Rosa and 6 children inluding David M. Oken, University of Maryland School of Pharmacy graduate of 1958. After graduating, Lou worked approximately 15 years with the Read Drug and Chemical Company. He then purchased a pharmacy on Broadway (Oken's Rexall Pharmacy) in which he and his brother, Jack Oken ('46) were partners for 40 years. Jack and Lou also were partners in the Northern Rexall Pharmacy on Northern Parkway. Dr. Louis Oken retired from the business in 1980.

Dr. Meyer M. Baylus ('26) passed away on March 18, 1989. He was an eye, ear, nose and throat specialist for 56 years in the Baltimore area. Dr. Baylus was survived by his wife, Louise, 2 daughters and 5 brothers.

Spotlights

Spotlight on William W. Resser–"The Train Buff"

Bill Resser ('59) has been a train lover for many years. He is a charter member of the Western Maryland Chapter of the National Railway Historical Society and now serves on the board of directors of this group, headquarted in the Western Maryland Station Center in downtown Cumberland. This chapter has been instrumental in the renovation of the Western Maryland Station Center, formerly a passenger terminal and office center on Western Maryland Railway. An Offshoot of this activity has been the ongoing renovation and upgrading of the old Western Maryland mail line between Cumberland and Frostburg. The 13 mile-long line will be called the Alleghany Central Railway and feature steam locomoting draw passenger trains for tourist service.

Bill and wife, Mary Sue, live at home in Pinto, Maryland with their 3 youngest daughters Amy, Susie, and Kathy. Their oldest daughter, Maryanne, was married recently to Jeffrey H. Herndon of Williamsport. After working many years with Drug Fair, William now works part time at the Medicine Shoppe in Frostburg and Walsh and McCagh Pharmacy in Cumberland.

New Pharmacies

Best Care Pharmacy
800 Pershing Drive
Silver Spring, MD 20910

Giant Pharmacy #1198
9812 Falls Road
Potomac, MD 20854

Thrift Drug #7366
Wildwood Shopping Center, Rt. 235
California, MD 20619

Nutricare
Rt. 5 Box 172-0, Regan Bldg.
Leonardtown, MD 20650

Klein's Pharmacy of Bel Air
223 N. Main Street
Bel Air, MD 21014

Drug Emporium (3)
6320 Ritchie Hwy.
Glen Burnie, MD 21062

Rite Aid #2269
3458 Emmorton Road
Abingdon, MD 21009

Weis Pharmacy #114
3482 Emmorton Road
Abingdon, MD 21009

Home Care Pharmacy/Fennel
324 E. Antietam Street
Hagerstown, MD 21740

People's Drug Store 1104
761 E. Wilson Blvd.
Hagerstown, MD 21740

People Drug #1481
134 MacArthur Blvd.
California, MD 20619

Team Care, Inc.
Washington Branch
4014 Blackburn Lane
Burtonsville, MD 20866

Martin's Pharmacy
Fountainhead Plaza
Pennsylvania Avenue
Hagerstown, MD 21740

People's Drug #1469
1080 W. Patrick Street
Suite 2
Frederick, MD 21701

Fantle's Drug Store #296
18149 Town Center Drive
Olney, MD 2083

Continued on page 20. . . .

For treatment of diabetes:

Introducing
Humulin® 70/30
70% human insulin isophane suspension
30% human insulin injection
(recombinant DNA origin)

REPLACE
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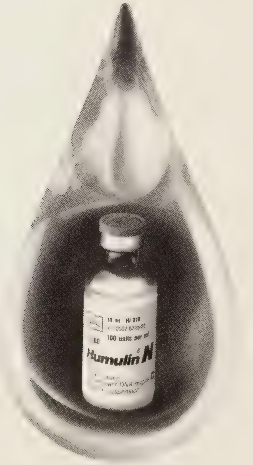

Humulin®
human insulin
(recombinant DNA origin)

Any change of insulin should be made cautiously and only under medical supervision.

Lilly
Leadership
In Diabetes Care

1989 ELI LILLY AND COMPANY HI-2914-B 949334

The 1989 Compiled Lilly Digest Statistics

TABLE 1
LILLY DIGEST AVERAGES OF SELECTED OPERATING STATISTICS**

AVERAGES PER PHARMACY	1988 MARYLAND (24 Pharmacies)	1988 SOUTH ATLANTIC REGION (256 Pharmacies)	1988 AVERAGE UNITED STATES (1,858 Pharmacies)
SALES			
Prescription	$ 562,520— 71.0%	$ 513,413— 70.6%	$ 529,360— 68.9%
Other	229,678— 29.0%	213,379— 29.4%	238,452— 31.1%
Total Sales	$ 792,198—100.0%	$ 726,792—100.0%	$ 767,812—100.0%
COST OF GOODS SOLD	555,036— 70.1%	495,559— 68.2%	525,731— 68.5%
GROSS MARGIN	$ 237,176— 29.9%	$ 231,233— 31.8%	$ 242,081— 31.5%
EXPENSES			
Proprietor's or Manager's salary	$ 58,939— 6.4%	$ 46,956— 6.5%	$ 45,535— 5.9%
Employees' Wages	69,352— 8.8%	68,994— 9.5%	72,658— 9.5%
Rent	19,733— 2.5%	17,305— 2.4%	17,976— 2.3%
Miscellaneous Operating Expenses	77,847— 9.8%	74,616— 10.2%	82,662— 10.8%
Total Expenses	$ 217,871— 27.5%	$ 207,871— 28.6%	$ 218,831— 28.5%
NET PROFIT (before taxes)	$ 19,291— 2.5%	$ 23,362— 3.2%	$ 23,250— 3.0%
Add proprietor's withdrawal	50,939— 6.4%	46,956— 6.5%	45,535— 5.9%
TOTAL PROPRIETORS INCOME	70,230— 8.9%	$ 70,318— 9.7%	$ 68,785— 9.0%
VALUE OF INVENTORY AT COST AND AS A PERCENT OF SALES			
Prescription	$ 58,194— 10.3%	$ 58,429— 11.4%	$ 53,931— 10.2%
Other	45,398— 19.8%	36,657— 17.2%	50,817— 21.3%
Total Inventory	$ 103,592— 13.1%	$ 95,086— 13.1%	$ 104,748— 13.6%
ANNUAL RATE OF TURNOVER OF INVENTORY	5.5 times	5.3 times	5.1 times
FLOOR AREA*	1,838 sq. ft.	2,860 sq. ft.	2,879 sq. ft.
SALES PER SQUARE FOOT*	$ 431.12	$ 252.62	$ 264.88
RENT PER SQUARE FOOT*	$ 10.74	$ 6.05	$ 6.24
NUMBER OF PRESCRIPTIONS DISPENSED			
New	20,665— 64.4%	16,850— 54.3%	17,210— 54.0%
Renewed	11,435— 35.6%	14,162— 45.7%	14,681— 46.0%
Total Prescriptions	32,100—100.0%	31,021—100.0%	31,891—100.0%
PRESCRIPTION CHARGE	$17.52	$16.56	$16.60
NUMBER OF HOURS PER WEEK			
Pharmacy was open	66 hours	60 hours	60 hours
Worked by proprietor	48 hours	56 hours	54 hours
Worked by employed pharmacist(s)	43 hours	26 hours	30 hours
PERCENT OF TOTAL PRESCRIPTIONS COVERED BY:			
Medicaid	15.3%	16.3%	16.8%
Other Third Party	32.6%	18.4%	23.5%

* Based on averages of pharmacies that reported all data.

** Source: 1989 *Lilly Digest*.

F & M Pharmacy #50
Route 301
Waldorf, MD 20601

People's Drug Store #1478
5644 Silver Hill Road
District Heights, MD 20747

Pharmacy Closings

Valu Pharmacy #2
10 Stemmers Run Road
Essex, MD 21221

Fantle Drug #186
5820 Silver Hill Road
District Heights, MD 20747

Laurel Medical Pharmacy
321 Prince George Street
Laurel, MD 20810

Alameda Pharmacy
5658 The Alameda
Baltimore, MD 21239

New I.V. Pharmacy
Medical Care Home Health
Resources
2921 E. Biddle Street
Baltimore, MD 21213

Walkersville Pharmacy
13 W. Frederick Street
Walkersville, MD 21793

Rite Aid #278
Cross Roads Shopping Center
Westminster, MD 21157

Prescription Center Pharmacy
9131 Piscataway Road
Clinton, MD 20735

New Addresses

Alternative Home Care
5910 York Road
Baltimore, MD 21212
(Formerly: 110 W. Madison St.)

Rite Aid 3837
Route 13 & Linden Avenue
Pocomoke City, MD 21891
(Formerly: 1404 Market St.)

Prescription Health Center
8106 Harford Road
Baltimore, MD 21234
(Formerly: 8109 Harford Road)

Eakles Drug Store
201 N. Burhans Blvd.
Hagerstown, MD 21740
(Formerly: 425 Pennsylania Ave.)

Village Drugs
Route 5, Old Line Center
Waldorf, MD 20604
(Formerly: Route 5, Box 446)

New Ownership and Name

Edgehill Pharmacy (5)
14310 Coastal Hwy
Ocean City, MD 21842
(Formerly: Ocean Drugs)

Home Care Center Pharmacy
251 E. Antietam Street
Hagerstown, MD 21740
(Formerly: Antietam Health)

Mulvey's Preston Pharmacy
P.O. Box 129 Main Street
Preston, MD 21655
(Formerly: Preston Pharmacy)

West Baltimore Medical Center
1501 W. Saratoga Street
Baltimore, MD 21223
(Formerly: 1701 W. Pratt St.)

Member Letters

Dear Pharmacy Employer/Employee Relations Committee:

As a retail pharmacist in the community sector, a major problem that we have identified and would like to have MPhA address is that of incomplete prescriptions. This concerns both controlled and non-controlled substances, and seems to be primarily limited to hospitals, walk-in clinics, and health department clinics. In particular, we are speaking of prescriptions lacking legible signatures, D.E.A. numbers, physician's printed name and phone number, and clear source (e.g. prescriptions written without indicating their department of origin clinic, E.R., and the like).

These prescriptions are difficult to handle, especially during the evening hours; since, frequently the M.D.'s signature is illegible and is not printed, the phone number of the original source of the Rx is frequently missing, etc. So, the point is: if an M.D. whose name I cannot make out writes for Feldene 10 mg, to be taken as 12 tablets! B.I.D., and I cannot make out or reach the doctor, how do I resolve the situation??

But, even worse: suppose the prescription is for a controlled substance and is missing the D.E.A. number. In an honest mistake how might I reconcile this situation? Do I send it on down the line to another pharmacy to deal with?? I trust most of you would not like such a practice.

Continued on page 23. . . .

THE
DRUG HOUSE
an ALCO HEALTH SERVICES company

ATTENTION
MR. INDEPENDENT RETAILER

BELOW ARE 7 IMPORTANT QUESTIONS THAT COULD EFFECT THE FUTURE OF YOUR PHARMACY.

1. IS YOUR CUSTOMER BASE ERODING DUE TO DEEP DISCOUNT COMPETITION?
2. ARE YOUR PRESCRIPTION CUSTOMERS BUYING THEIR HBA'S FROM YOUR COMPETITION? (CHAINS, MASS MERCHANDISERS, GROCERY STORES)
3. ARE YOUR HEALTH AND BEAUTY AIDS PRICES COMPETITIVE?
4. IF SO, ARE YOU TELLING YOUR CUSTOMERS?
5. HAS INCREASED THIRD PARTY PRESCRIPTIONS AND COMPETITION AFFECTED YOUR PRESCRIPTION DEPARTMENT PROFIT?
6. ARE YOU TIRED AND CONFUSED FROM SEARCHING FOR THE BEST SOURCE OF SUPPLY, AT THE BEST PRICE, TO FILL YOUR O.T.C. AND PHARMACEUTICAL NEEDS?
7. ARE YOU INTERESTED IN A TOTAL PROGRAM THAT WILL SOLVE ANY OR ALL OF THE ABOVE?

ASTRO
SUPER SAVERS

THE DRUG HOUSE
BALTIMORE/WASHINGTON DIVISION
301-467-2780

PATRICK L. HRUZ
SALES MANAGER

USP
DRUG PRODUCT QUALITY
Review
A PUBLICATION OF THE USP DRUG PRODUCT
PROBLEM REPORTING PROGRAM

No. 9 INJECTABLE CONCENTRATES TO BEAR LABEL DESIGNATION

Each year the USP DPPR receives many reports regarding the similarity in appearance of containers, packaging, and/or labeling of various injectable products. Practitioners have expressed their concern that the similarity in appearance could lead to administration of an improper dose or of an incorrect product.

Similarity in the appearance of containers as well as hasty or careless reading of the label may result in misadministration of a product. Medication errors due to the accidental injection of concentrated potassium solution instead of the diluted solution are well documented. The mistakes resulted from either the undiluted product being administered by direct IV injection or the concentrated Potassium Chloride Injection being mistakenly used in place of another drug such as Isotonic Sodium Chloride Injection or Aminophylline Injection. One reporter suggested the obvious—that a caution be required on labels which would make it difficult to confuse the products.

• • •

USP Review

Due to the high number of medication errors involving concentrated solutions for injection, the USP Nomenclature Committee has proposed the renaming of injections which must be diluted prior to use. Because Potassium Chloride Injection has been involved in many reported accidental misuses, the USP is proposing to begin the renaming of injection concentrates with this monograph, by changing the title of **Potassium Chloride Injection** to **Potassium Chloride for Injection Concentrate**.

In addition to the name change, additional requirements for the label and the closure system are being proposed. On the label, the word "Concentrate" will be required to appear in a contrasting color, or in a contrasting or bolder type. The closure system will be required to prominently display the statement "Must be Diluted" in a manner that will be visible at the time the contents are withdrawn. For example, on containers with stoppers held in place by metal overseals, the information can appear on the surface of the seal surrounding the stopper top. For ports in flexible plastic containers, the monograph allows the same statement to be printed on the container surface immediately surrounding the port.

While these proposed changes cannot take the place of careful label reading, it is hoped that the title change along with the additional labeling requirements will decrease the likelihood of mistaking the concentrate for a ready-to-use solution, or another drug.

These changes are being proposed in the July-August 1989 *Pharmacopeial Forum*, with the intent that they be made official in an Interim Revision Announcement.

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Issued 8/89

In an effort to attend to the needs of my patients and customers, and at the same time avoid filling forged prescriptions for controlled substances, (which may or may not be valid, as there is little way to verify such), we are challenging ourselves, our fellow pharmacists and others who recognize this problem to identify and implement practical solutions. We are at your disposal and will do whatever is necessary to see that a resolution to this problem is reached.

Respectfully submitted,

Loretta Holmes, R.N.
4th year Pharmacy Student

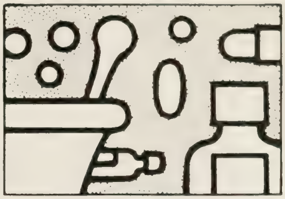
Rick Thompson, P.D.
Pharmacy Manager
PEP Preceptor
Safeway #126
Upper Marlboro.

You're never too old to quit blowing smoke.

No matter how long or how much you've smoked, it's not too late to stop. Because the sooner you put down your last cigarette, the sooner your body will begin to return to its normal, healthy state.

American Heart Association
WE'RE FIGHTING FOR YOUR LIFE

Things You Should Know FOR YOUR GOOD HEALTH



Get to Know Your Plants

Observance of National Poison Prevention week is slated each year for the third week in March. Recognized by Congress since 1961, this week is officially set aside to encourage local communities to raise the awareness of the dangers of accidental poisonings and to instruct the public about poison prevention and treatment.

We all understand the potential poisoning hazard of household chemicals such as detergents, cleansers, pesticides, weed killers and other products. Also much publicized is the danger represented by prescription and over-the-counter medications when left within the reach of children. These chemicals and drug products should be stored securely and out of the way of adventuresome youngsters.

Other less evident potential killers in many of our households are plants and flowers. Beautiful around the house, many plants and flowers are deadly if eaten. Some of the more common poisonous plants are amaryllis, azalea, daffodil, jonquil, English ivy, gladiola, iris, lily-of-the-valley, peony, and plants of the philodendron family. Included in the list of poisonous plants are some traditional Christmas plants, including poinsettia, holly, and mistletoe.

Some of these plants pose greater dangers than others. Effects of plant poisonings may range from nausea, vomiting, and stomach cramping to unconsciousness and death.

A good way to avoid accidental poisoning due to house plants is to know your plants. Many of us buy house plants based on their appearance and may have no idea of its name or species. Go to your public library or local green house to identify these biological beauties.

For further information concerning the potential toxicity of many household plants, along with first aid recommendations and to get a free copy of **"What About Plants?"**, send a self-addressed stamped envelope to: Secretary-Treasurer, American Association of Poison Control Centers, 2025 I. St. N.W., Suite 105 Washington, D C 20006.

To learn more about storage and handling of your medications and other household chemicals, **Ask Your Pharmacist**. It's For Your Good Health.

© SPEA

The Right prescription for all pharmacy owners...

THE MAYER and STEINBERG / MARYLAND PHARMACISTS ASSOCIATION WORKERS' COMPENSATION PROGRAM

OFFERING AN IMMEDIATE **20% DISCOUNT** PLUS ELIGIBILITY FOR UP TO A **25% DIVIDEND** AFTER POLICY EXPIRES

Maintain the same coverage now provided by your Workers' Compensation Insurance...BUT... dramatically reduce your premium costs.

Now...Better Than Ever...Mayer and Steinberg is the best prescription for insurance for the Pharmacist.

PRESCRIPTIONS

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Play Your Cards Right...

Maryland Pharmacists Association

108th Annual Convention

June 17-21, 1990

Sheraton Ocean City Resort Hotel

An Invitation

As President of MPhA this year, I want to extend a personal invitation to every member to attend the 1990 Annual Convention.

This year, convention attendees can earn 13 continuing education credits towards their relicensure requirements. Our business meetings have been streamlined to give everyone a chance to participate in the Association's activities.

As for social events, along with the fun and feast of the Annual Crab and Chicken Feast, we've included a Monte Carlo Casino Nite to give everyone a chance to try their luck.

If you've never attended a MPhA Convention, this is the year to give us a try. Go ahead and take a gamble. You're guaranteed to come out a winner!

Nathaniel Futeral, P.D.
President

Social Events

Come roll the dice for fun with MPhA. This year's convention is full of excellent opportunities to network and socialize with your colleagues. From our opening Health Food Welcoming Reception on Sunday, June 17 to our Annual Awards and Installation Banquet on Wednesday, June 20, you'll be guaranteed a good time.

And you won't go home hungry! Join us every morning for breakfast, donuts and coffee during seminar breaks, luncheon in the exhibit hall each afternoon, and plenty of evening receptions and parties.

Our President's Reception wil be an event you won't want to miss. Our Monte Carlo Casino Nite will let you try your luck at games of chance, dance to big band music, and sample delicious hors d'oeuvres. You'll want to break out the jewels and tuxedos for this one!

Tentative Program

Sunday, June 17, 1990

1:00-5:00 pm	Registration
2:00-4:00 pm	Welcoming Reception
4:00-6:00 pm	Continuing Education Seminar
9:00-11:00 pm	Cocktail Party

Monday, June 18, 1990

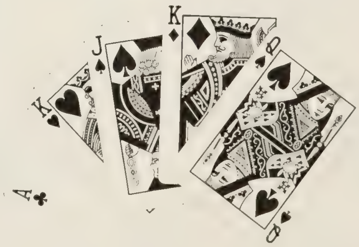
8:00-9:00 am	Bagel Breakfast
9:00-11:30 am	Continuing Education Seminar
10:00-12:00 am	SAMPA Brunch and Fashion Show
11:30-12:30 pm	MPhA House of Delegates Business Session Reports to the Membership
12:30-2:30 pm	Trade Exposition and Luncheon
2:30-4:30 pm	Continuing Education Seminar
6:30-10:00 pm	Crab and Chicken Feast Old Time Hoe Down

Tuesday, June 19, 1990

8:00-9:00 am	Bagel Breakfast
9:00-12:30 am	Continuing Education Seminar
10:00-12:00 am	SAMPA Brunch and Seminar
12:30-2:30 pm	Trade Exposition and Luncheon
2:30-4:30 pm	Continuing Education Seminar
9:00-12:00 pm	Monte Carlo Casino Nite

Wednesday, June 20, 1990

8:00-9:00 am	Continental Breakfast
9:00-10:00 am	Continuing Education Seminar
10:00-12:00 am	MPhA House of Delegates Resolutions and Officers Installation
6:00-7:00 pm	Annual Banquet Reception
7:00-9:00 pm	MPhA Annual Awards Banquet



Accommodations

Once again, the Maryland Pharmacists Association has been able to obtain for attendees discounted hotel rates for one of Ocean City's finest resort hotels. In previous years, the hotel sold out of reserved rooms at the special MPhA convention rate.

Don't be disappointed! Complete the enclosed reservation request form and mail it directly to the Sheraton Ocean City Resort. All room reservations must be received by the hotel no later than May 10, 1990. MPhA nor the Sheraton can guarantee space availability at these rates after the deadline.

Children under 17 stay free of charge in same room as parents. Rates are subject to 8 percent room tax. One night deposit is required. Rooms are available for check-in at 3:00 pm. The Sheraton Ocean City Resort accepts personal checks for deposit only. No personal checks will be accepted after arrival. Credit cards are not accepted for advance deposit. A 72-hour cancellation or change notice is required.

Room Rates

Guest Rooms (per night)

Single/Double	$123	Cabana Suites	$240
Triple	$137	Studio Suites	$180
Quad	$151		

Condominiums (per week)

With Maid Service	$1,000
Without Maid Service	$ 800

Registration

To register for the 108th Annual Convention of the Maryland Pharmacists Association, complete the registration form on the back of this brochure. Please print or type clearly. Return the form, with your check or money order for the total convention registration to the MPhA offices.

Admission to all functions will be by ticket or badge. Pick up badges and other registration materials at the MPhA Registration Desk beginning Sunday, June 17 at 1:00 pm or on Monday, June 18 at 8:00 am. You must register with the MPhA Convention to take advantage of special convention hotel rates. Spouses must register or purchase function tickets to attend any special activities.

Full MPhA or Spouse/Guest Registration includes admission to all meetings, social events, and continuing education credits. Single Day registration includes all meetings and social events for that day only. Single Day registrants should indicate which day they plan to attend.

Registration Fees	**Before April 15**	**After April 15**
MPhA Convention		
MPhA Member	$ 85	$105
Spouse/Guest	$ 75	$ 95
Non-Member	$135	$155
Single Day	$ 50	$ 70
Pharmacy Student	no charge	no charge
Children under 18	no charge	no charge
Crab and Chicken Feast		
Extra Adult/Students	$ 20	$ 25
Children und er 12	$ 10	$ 15
MPhA Annual Banquet		
Extra Adult/Students	$ 22	$ 27
Children Under 12	$ 17	$ 22
SAMPA Functions (included in Spouse fee)		
Monday Fashion Show	$ 10	$ 15
Tuesday Seminar	$ 10	$ 15

Trade Exposition

Keep up with the latest, most exciting developments and the newest products on the market at the MPhA Trade Exposition. Visit every exhibitor and enter to win the Grand Prize Sweepstakes!

Don't forget to join us for lunch in the Exhibit Hall on Monday, June 18, and Tuesday, June 20 from 12:30 to 2:30 pm.

Registration Form

Registration Fees
(indicate number)

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Name ____________________

Nickname for Badge ____________________

Pharmacy/Company Name ____________________

Mailing Address ____________________

City/State/Zip Code ____________________

Phone ____________________

Spouse/Guest Name ____________________

Children Name ____________________

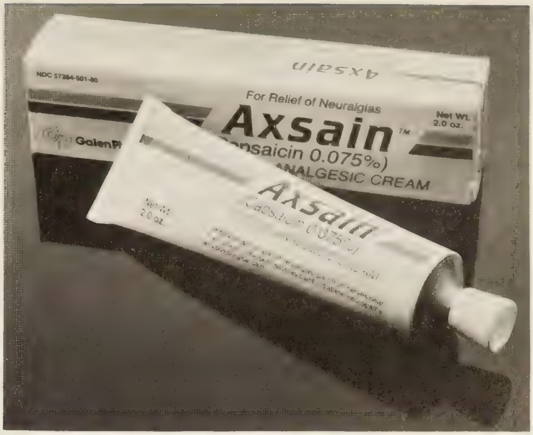
Return registration form with payment to:

MPhA Convention Registration
Kelly Memorial Building
650 West Lombard Street
Baltimore, Maryland 21201-1572

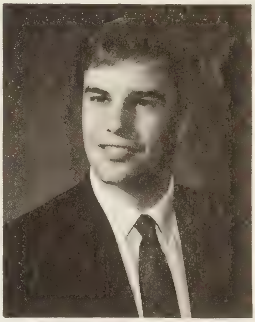
NDC 55077-720-01
MULTILYTE
Effervescent Multivitamin and Mineral Supplement
Natural orange flavor
Each tablet safety-sealed.
12 Effervescent tablets.
IHP

IHP's Multilyte, a new effervescent vitamin, has significant clinically proven advantages over tablet forms of vitamins including: faster absorption into the bloodstream and more complete absorption.

AM FAB is proud to announce its new Model 4500CU Overbed Table that's quality-crafted and priced for today's value-conscious acute-care professionals. For complete information call AM FAB at (616) 385-2938.


For Relief of Neuralgias
Axsain
Capsaicin 0.075%
ANALGESIC CREAM
Net Wt. 2.0 oz.

GalenPharma, Inc. has begun supplying pharmacies nationwide with Axsain (capsaicin 0.075%), a new nonsystemic medication that is the first analgesic to be demonstrated effective in easing the pain of peripheral diabetic neuropathy.



Debra L. Knights, a graduate of Southern Nazarene University, has been assigned to the Bethesda territory for The Upjohn Company. She recently completed initial training at Upjohn in Kalamazoo.

Albert S. Copersino has been assigned to the Washington territory for The Upjohn Company after receiving extensive training at The Upjohn Company Learning Center. Al is a graduate of the University of Virginia.

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Continuing Education Quiz

The Maryland Pharmacist DECEMBER, 1989

Complete and mail entire page with $5.00 check, $10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received March 31, 1990. A continuing education certificate for one contact credit) will be mailed to you within 30 days. Please type or print clearly.

Name ____________________

Social Security Number ____________________

Address ____________________

City/State/Zip ____________________

Is this program used to meet your mandatory CE? [ ] Yes [ ] No

Did this article achieve its stated objectives? [ ] Yes [ ] No

How long did it take you to complete the program? __________ minutes

OTC Analgesics: Acetaminophen

1. Self-medication with OTC analgesics is most appropriate for which of the following types of pain?
   a. Frequent headache
   b. Lower back pain that comes and goes
   c. Joint pain that flares up on occasion
   d. Pain associated with mild osteoarthritis

2. Acetaminophen overdose is most likely to cause toxic effects on the:
   a. liver.
   b. heart.
   c. lungs.
   d. colon.

3. Acetaminophen is a major metabolite of:
   a. phenacetin.
   b. acetylsalicylic acid.
   c. propoxyphene.
   d. acetylcysteine.

4. The drug interaction that is reported to have the greatest potential for significance is between acetaminophen and:
   a. acetohexamide.
   b. tranylcypromine.
   c. warfarin.
   d. zidovudine.

5. The potential result of the interaction described in question #4 above is that acetaminophen:
   a. decreases the metabolism of warfarin.
   b. is inhibited by acetohexamide.
   c. increases the toxicity of zidovudine.
   d. is potentiated by tranylcypromine.

6. Agranulocytosis is a blood dyscrasia that refers to reduced levels of:
   a. blood platelets.
   b. red blood cells.
   c. granuloma cells.
   d. white blood cells.

7. Which of the following is *not* recommended for use in treating patients suffering from an overdose of acetaminophen?
   a. Ipecac syrup
   b. Activated charcoal
   c. Gastric lavage
   d. Acetylcysteine

8. With regard to alleviating pain or fever, on a milligram-to-milligram basis, acetaminophen is best described as being:
   a. less effective than aspirin.
   b. equally effective as aspirin.
   c. more effective than aspirin.

9. OTC analgesics are most effective in alleviating which of the following types of pain?
   a. Sharp
   b. Moderate
   c. Severe
   d. Protracted

10. The amino acid that reacts with the potentially toxic metabolite of acetaminophen to form a nontoxic substance is:
    a. ascorbic acid.
    b. cytosine.
    c. glutathione.
    d. tryptophan.

Classifieds

PHARMACIST WANTED for full and part-time positions available. Benefits include health insurance, paid vacation and NO evening hours in a computerized independent pharmacy located on the Eastern Shore. Call Fred Beatie at (301) 742-1188 or (301) 742-0914 to discuss this exciting opportunity.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Santi V. Lusco at 254-1772.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

ATTENTION—HIRING! Government jobs—your area. Many immediate openings without waiting list or test. $17,840–$69,485. Call 1-602-838-8885. Extension 9494.

PHARMACY COMPUTER System for sale. 3PM 40/40, 5 years old, Best offer. Call Brian at Penn-Dol, (301) 669-2424.

EVERY SUNDAY MORNING at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the pharmacy public relations program, "Your Best Neighbor," the oldest continuous public service show in Baltimore.

PHARMACY FOR SALE. Well-established pharmacy on Eastern Shore of Maryland. Great hunting and fishing, close to beaches. $420,000 volume, 87% prescription and OTC. Call (301) 957-1648 after 8 pm.

PART TIME PHARMACIST to be utilized when regular pharmacist is on vacation and unexpected periods of illness. No weekends or holidays designated by the State of Maryland. Position is located at a State hospital. If interested, contact Emanuel G. Freeman, P.D., 6524 Copper Field Road, Baltimore, MD 21209. Work number (301) 792-4022.

PHARMACISTS REHABILITATION COMMITTEE HOTLINE is (301) 727-0746.

FDA HOTLINE FOR AIDS information is 800-432-AIDS.

HGP CLEANER by Coopervision wanted. Call (301) 655-2060.

FOR SALE One used Drustar Model 3 Drug Cart with accessories plus six cassettes with drawers. Contact Ken Whittemore in Hagerstown at (301) 791-5220.

FOR RENT St. Thomas, U.S. Virgin Islands Condominium (weekly rental). Two bedrooms, two baths, overlooks the Caribbean on the beach. Ideal for two couples or family. Please contact: Dr. Steven J. Berlin, (301) 247-4770, evenings: (301) 252-7508.

DRUG INFORMATION ANALYST AHFS DI 90: This position, within ASHP's Database Services Division, is responsible for assisting in the preparation of the American Hospital Formulary Service, D.I. 90, the leading evaluative drug information compendium. Applicants must: be graduates of a college of pharmacy; have strong background in pharmacology, clinical use of drugs and appreciation of drug information needs of health practitioners; have proven competence in the evaluation, clinical selection and utilization of drug literature; demonstrate exceptional writing skills; have a minimum of two years practice experience.

DIRECTOR STATE REGULATORY AFFAIRS DEPARTMENT: This position, within the Expanded Government Affairs Division, will be responsible for: monitoring and identifying State issues of interest to ASHP and its affiliates; recommending actions to implement policy at State level; serving as liaison and resource to State regulatory agencies; submitting written comments to State bodies; making presentations to ASHP members on State regulatory issues. Successful candidate will have at least two years of experience in State regulatory affairs, exposure to pharmacy related issues, association experience, ability to present issues clearly before the public, and proven exceptional writing and speaking skills.

ASSISTANT EDITOR SPECIAL PROJECTS DIVISION: This position, within ASHP's highly successful Special Projects Division will identify and produce new multimedia publications (primarily books); coordinate work of contributors and prepare and edit copy for publication projects directed to practitioners in organized health care settings. Qualifications will include pharmacy degree, exceptional writing skills, ASHP-accredited residency or equivalent hospital pharmacy practice experience, attention to detail, familiarity with pharmacy literature and appreciation of the information needs of practitioners.

The Views We Get Make It Well Worth The Trip.

The 12 members of our Pharmacy Consultant Panel bring viewpoints from a wide variety of disciplines all around the country. And our summer meeting is a special time to get together—a time to share views, ideas and experiences with an outlook to future professional needs.

For three days every summer, the panel members come together to talk, to listen, to share their enthusiasm and their commitment to the pharmacy profession and its bright future. We share that commitment—and keeping in touch with them helps us keep in touch with you and your concerns. Working together gives us all a better view of the future—and how to make it brighter.

Upjohn

The 1989 Pharmacy Consultant Panel—Left to Right:

Henri R. Manasse, Jr.
Dean, College of Pharmacy
University of Illinois at Chicago
Chicago, Illinois

Thomas R. Temple
Executive Vice President
Iowa Pharmacists Association
Des Moines, Iowa

John H. Vandel
President
Vandel Drugs, Inc.
Torrington, Wyoming

Margaret M. Chrymko
Assistant Director
Clinical Pharmacy Services & Research
Hamot Medical Center
Erie, Pennsylvania

John K. Middleton
President, Pharmacy Programs
United HealthCare Corporation
Minneapolis, Minnesota

Calvin H. Knowlton
Owner, Amherst Pharmacy, Inc.
Lumberton, New Jersey

C. Fred Toney
Sr. Vice President
Sales & Merchandising
McKesson Drug Company
San Francisco, California

Herman L. Lazarus
Director, Department of Pharmacy
University of Alabama Hospitals & Clinic
Birmingham, Alabama

Nelson L. Showalter
President
Williamson's Pharmacy
Harrisonburg, Virginia

Thomas M. Ryan
Sr. Vice President
Pharmacy Operations
Consumer Value Stores
Woonsocket, Rhode Island

William A. Gouveia
Director of Pharmacy
New England Medical Center
Boston, Massachusetts

John J. Fegan (not pictured)
Vice President
Pharmacy Operations
Pay 'N Save Inc.
Seattle, Washington